The study listed may include approved and non-approved uses, formulations or treatment regimens. The results reported in any single study may not reflect the overall results obtained on studies of a product. Before prescribing any product mentioned in this Register, healthcare professionals should consult prescribing information for the product approved in their country.

Study No.: 109817 (H5N1-015)

Title: Evaluate the reactogenicity and immunogenicity of one or two booster administrations of an influenza pandemic candidate vaccine (GSK1562902A) in primed adults aged between 19 and 61 years.
GSK1562902A: GlaxoSmithKline Biologicals' approved formulation of influenza pandemic vaccine (H5N1)

Rationale: The study was designed to evaluate the immune response induced by one or two booster doses of H5N1 derived from A/Indonesia/5/05 strain when administered to subjects primed in H5N1-007 (106750) study with the pandemic H5N1 vaccine (adjuvanted or non-adjuvanted) derived from A/Vietnam/1194/04 strain. A group of unprimed subjects were used as control and received 2 doses of the H5N1 in this current study.
Please refer to the CTRS on H5N1-007 (106750) for the data on the primary vaccination course.

Phase: II

Study Period: 02 August 2007 to 09 October 2009

Study Design: Open, non-randomized study with 9 parallel groups.

Centers: Single center in Belgium.

Indication: Immunization against influenza disease in subjects aged between 19 and 61 years.

Treatment: There were 9 groups in this booster study:

- 4 groups (H5N1/D1, H5N1/D2, H5N1/D3, and H5N1/D4) primed with 2 doses of a non-adjuvanted investigational formulation of H5N1 vaccine (A/Vietnam/1194/04 strain) in study 106750 received 2 doses of the approved H5N1 (A/Indonesia/5/05 strain) vaccine in this booster study, one at Day 0 and one at Day 21.

These 4 groups above are referred to as the non-AD groups.

- H5N1/D1/Adj Group: primed with 2 doses of the approved H5N1 vaccine (A/Vietnam/1194/04 strain) received 1 dose of the approved H5N1 (A/Indonesia/5/05 strain) vaccine at Day 0.
- 3 groups (H5N1/D2/Adj, H5N1/D3/Adj and H5N1/D4/Adj) primed with 2 doses of an adjuvanted investigational formulation of H5N1 vaccine (A/Vietnam/1194/04 strain) received 1 dose of the approved H5N1 vaccine (A/Indonesia/5/05 strain) at Day 0.

These 4 groups above are referred to as the AD groups.

- Control Group: unprimed subjects received 2 doses of the approved H5N1 vaccine, one at Day 0 and one at Day 21.

The vaccines were administered intramuscularly in the deltoid region of the non-dominant arm.

Objectives:

- To assess if the humoral immune response induced 21 days after one booster administration of H5N1 fulfils the criteria established by the European Committee for Medicinal Products for Human Use (CHMP) in subjects primed approximately 14 months earlier with two administrations (21 days apart) of the adjuvanted vaccine formulated from a heterologous strain.
- To evaluate the safety of H5N1 vaccine in terms of solicited local and general symptoms, unsolicited symptoms and serious adverse events.

Primary Outcome/Efficacy Variable:

Immunogenicity

For the humoral immune response in the groups primed with an adjuvanted vaccine (the AD groups)

Observed variables at Day 0 and Day 21, serum anti-haemagglutinin (HA) antibody titers against the A/Indonesia strain:
Derived variables (with 95% confidence intervals [CI]):

- Geometric mean titers (GMTs) of anti-HA antibody titers at Day 0 and Day 21.
- Seroconversion rates* (SCR) at Day 21.
- Seroconversion factors** (SCF) at Day 21.
- Seroprotection rates*** (SPR) at Day 0 and Day 21.

**Seroconversion rate for anti-HA antibody response is defined as the percentage of vaccinees who have either a pre-vaccination titer < 1:10 and a post-vaccination titer ≥ 1:40 or a pre-vaccination titer ≥ 1:10 and at least a 4-fold increase in post-vaccination titer*

***Seroconversion factor is defined as the fold increase in serum anti-HA antibody GMTs post-vaccination compared to Day 0.*

****Seroprotection rate is defined as the percentage of vaccinees with a serum anti-HA antibody titer ≥1:40 that usually is accepted as indicating protection.*

Safety

- Percentage, intensity and relationship to vaccination of solicited local and general signs and symptoms during a 7-day follow-up period (i.e. day of vaccination and 6 subsequent days) after each dose of vaccine and overall.
- Percentage, intensity and relationship to vaccination of unsolicited local and general signs and symptoms during a 21-day follow-up period after the first vaccination (i.e. day of first vaccination and 20 subsequent days) and a 30-day follow-up period after the second vaccination for non-adjuvanted vaccine and control groups, and during the 30-day follow-up period after the single vaccination for the adjuvanted vaccine group.
- Occurrence of serious adverse events (SAEs) during the entire study period.

Secondary Outcome/Efficacy Variable(s):

Immunogenicity

For the humoral immune response (in terms of both anti-HA antibodies and neutralizing$^{\delta}$ antibodies) the following parameters (with 95% CIs) were calculated for each group:

- GMTs of antibody titers at days 0, 7, 14, 21, 28, 35, 42, Month 6, Month 12, Month 18 and Month 24.
- SCR* at days 7, 14, 21, 28, 35, 42, Month 6, Month 12, Month 18 and Month 24.

In addition, humoral immune response in terms of anti-HA antibodies was evaluated using the following parameters (with 95% CIs):

- SCF** at days 7, 14, 21, 28, 35, 42, Month 6, Month 12, Month 18 and Month 24.
- SPR*** at days 0, 7, 14, 21, 28, 35, 42, Month 6, Month 12, Month 18 and Month 24.

$^{\delta}$*Neutralizing antibody testing was done in H5N1/D1, H5N1/D1/Adj and control groups only at Day 0, Day 21, Day 42, Month 6, Month 12, Month 18 and Month 24.*

** Seroconversion rate for neutralizing antibody response is defined as the percentage of vaccinees with a minimum 4-fold increase in neutralizing antibody titer at post-vaccination.*

***Seroconversion factor is defined as the fold increase in serum anti-HA antibody GMTs post-vaccination compared to Day 0.*

****Seroprotection rate is defined as the percentage of vaccinees with a serum anti-HA antibody titer $\geq$ 1:40 that usually is accepted as indicating protection.*

For the cell-mediated immunity response: for *H5N1/D1, H5N1/D1/Adj* and control groups, the following parameters (with 95% CI) were calculated at Day 0, Day 21, Month 6, Month 12, Month 18 and Month 24.

- Frequency of antigen-specific cytokine cluster of differentiation 4/8 (CD4/CD8) cells per 10^6 in tests identified as producing at least two out of four different cytokines (CD40 ligand [CD40L], Interleukin-2 [IL-2], Tumor necrosis factor-α [TNF-α], Interferon-γ [IFN-γ]) upon in vitro stimulation

Statistical Methods:

The analyses were performed on the Total Vaccinated Cohort, According-To-Protocol (ATP) cohort for immunogenicity and ATP cohort for persistence.

- The Total Vaccinated Cohort included all vaccinated subjects for whom data were available.
- The ATP cohort for immunogenicity included all evaluable subjects (i.e., those meeting all eligibility criteria, complying with the procedures defined in the protocol, with no elimination criteria during the study) for whom immunogenicity data were available. This included subjects for whom assay results were available for antibodies against at least one study vaccine antigen component after vaccination.The ATP Cohort for persistence consisted of all subjects who had serologic results available at the antibody persistence time point.

Analysis of immunogenicity

The analysis was performed on the ATP cohort for immunogenicity and on the ATP cohort for persistence.

For the humoral immune response in terms of both anti-HA antibodies (all groups) and neutralizing antibodies (*H5N1/D1, H5N1/D1/Adj and control groups only)*: at each time point when a serological result was available, the following data were tabulated: GMTs, SCR, SCF and SPR of anti-HA antibodies with 95% CIs.

For the H5N1/D1, H5N1/D1/Adj and control groups, the frequency of influenza-specific CD4/CD8 T lymphocytes was summarized (descriptive statistics) at Day 0, Day 21, Month 6, Month 12, Month 18, and Month 24.

Analysis of safety

The analysis was performed on the Total Vaccinated Cohort.

The percentage of subjects reporting each individual solicited local and general symptom during the 7-day (Day 0-6) solicited follow-up period was tabulated with exact 95% CI. The same tabulation was performed for grade 3 symptoms and for general symptoms with relationship to vaccination. The proportion of subjects with at least one report of unsolicited adverse event (AE) classified by the Medical Dictionary for Regulatory Activities (MedDRA) preferred terms and reported during a 21-day follow-up period after the first vaccination (i.e. day of first vaccination and 20 subsequent days) and a 30-day follow-up period after the second vaccination for non-AD and control groups, and during the 30-day follow-up period after the single

vaccination for the AD vaccine group was tabulated. The same tabulation was performed for grade 3 unsolicited AEs and for unsolicited AEs assessed by the investigator as related to the study vaccination. The occurrence of SAEs was tabulated according to MedDRA preferred terms during the entire study period.

Study Population: Healthy male or female subjects between 19-61 years of age at the time of first vaccination (for unprimed subjects) and subjects who previously participated in the study 106750 (for primed subjects) were included in the study. If the subject was female and of childbearing potential, she had to be abstinent or to have used contraceptive precautions for 30 days prior to vaccination; she was to have a negative pregnancy test at study entry and had to agree to continue contraceptive precautions for 2 months after completion of the vaccination series. Written informed consent was obtained from the subject prior to study entry.

Active phase of the study

Number of Subjects	**H5N1/D1 Group**	**H5N1/D 2 Group**	**H5N1/D 3 Group**	**H5N1/D 4 Group**	**Control Group**	**H5N1/D 1/Adj Group**	**H5N1/D 2/Adj Group**	**H5N1/D 3/Adj Group**	**H5N1/D 4/Adj Group**
Planned, N	50	50	50	50	50	50	50	50	50
Enrolled N (Total Vaccinated Cohort)	36	40	37	36	50	40	35	41	35
Completed to Day 51, n (%)	36 (100)	40 (100)	36 (97.3)	36 (100)	49 (98.0)	40 (100)	35 (100)	41 (10)	34 (97.1)
Total Number Subjects Withdrawn, n (%)	0 (0.0)	0 (0.0)	1 (2.7)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.9)
Withdrawn due to Adverse Events, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Withdrawn due to Lack of Efficacy, n (%)	NA	NA	NA	NA	NA	NA	NA	NA	NA
Withdrawn for other reasons, n (%)	0 (0.0)	0 (0.0)	1 (2.7)	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.9)
Demographics	**H5N1/D1 Group**	**H5N1/D 2 Group**	**H5N1/D 3 Group**	**H5N1/D 4 Group**	**Control Group**	**H5N1/D 1/Adj Group**	**H5N1/D 2/Adj Group**	**H5N1/D 3/Adj Group**	**H5N1/D 4/Adj Group**
N(Total Vaccinated Cohort)	36	40	37	36	50	40	35	41	35
Females : Males	18:18	19:21	16:21	21:15	34:16	27:13	18:17	23:18	18:17
Mean Age, years (SD)	36.3 (12.80)	36.3 (12.36)	36.8 (12.87)	39.5 (13.27)	32.1 (9.96)	38.5 (13.43)	38.3 (14.61)	34.8 (14.57)	35.9 (12.78)
White - Caucasian / European heritage, n (%)	36 (100)	38 (95.0)	37 (100)	36 (100)	48 (96.0)	40 (100)	34 (97.1)	41 (100)	35 (100)

Month 12 Results

Number of Subjects	**H5N1/D1 Group**	**H5N1/D 2 Group**	**H5N1/D 3 Group**	**H5N1/D 4 Group**	**Control Group**	**H5N1/D 1/Adj Group**	**H5N1/D 2/Adj Group**	**H5N1/D 3/Adj Group**	**H5N1/D 4/Adj Group**
Completed to Month 12, n (%)	36 (100)	40 (100)	36 (97.3)	35 (97.2)	48 (96.0)	40 (100)	35 (100)	41 (100)	34 (97.1)
Total Number Subjects Withdrawn, n (%)	0 (0.0)	0 (0.0)	1 (2.7)	1 (2.8)	2 (4.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.9)
Withdrawn due to Adverse Events, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Withdrawn due to Lack of Efficacy, n (%)	NA	NA	NA	NA	NA	NA	NA	NA	NA
Withdrawn for other reasons, n (%)	0 (0.0)	0 (0.0)	1 (2.7)	1 (2.8)	2 (4.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.9)
Demographics	**H5N1/D1 Group**	**H5N1/D 2 Group**	**H5N1/D 3 Group**	**H5N1/D 4 Group**	**Control Group**	**H5N1/D 1/Adj Group**	**H5N1/D 2/Adj Group**	**H5N1/D 3/Adj Group**	**H5N1/D 4/Adj Group**
N (Total Vaccinated Cohort)	36	40	37	36	50	40	35	41	35
Females : Males	18:18	19:21	16:21	21:15	34:16	27:13	18:17	23:18	18:17

Mean Age, years (SD)	36.3 (12.80)	36.3 (12.36)	36.8 (12.87)	39.5 (13.27)	32.1 (9.96)	38.5 (13.43)	38.3 (14.61)	34.8 (14.57)	35.9 (12.78)
White - Caucasian / European heritage, n (%)	36(100)	38 (95.0)	37 (100)	36 (100)	48 (96.0)	40 (100)	34 (97.1)	41 (100)	35 (100)
Month 18 Results									
Number of subjects	**H5N1/D1 Group**	**H5N1/D2 Group**	**H5N1/D3 Group**	**H5N1/D4 Group**	**Control Group**	**H5N1/D1/Adj Group**	**H5N1/D2/Adj Group**	**H5N1/D3/Adj Group**	**H5N1/D4/Adj Group**
Completed to Month 18, n (%)	33 (91.7)	37 (92.5)	31 (83.8)	33 (91.7)	40 (80.0)	38 (95.0)	33 (94.3)	35 (85.4)	32 (91.4)
Total Number Subjects Withdrawn, n (%)	0 (0.0)	0 (0.0)	1 (2.7)	1 (2.8)	2 (4.0)	0 (0.0)	0 (0.0)	1 (2.4)	1 (2.9)
Withdrawn due to Adverse Events, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.9)
Withdrawn due to Lack of Efficacy, n (%)	NA	NA	NA	NA	NA	NA	NA	NA	NA
Withdrawn for other reasons, n (%)	0 (0.0)	0 (0.0)	1 (2.7)	1 (2.8)	2 (4.0)	0 (0.0)	0 (0.0)	1 (2.4)	0 (0.0)
Demographics	**H5N1/D1 Group**	**H5N1/D2 Group**	**H5N1/D3 Group**	**H5N1/D4 Group**	**Control Group**	**H5N1/D1/Adj Group**	**H5N1/D2/Adj Group**	**H5N1/D3/Adj Group**	**H5N1/D4/Adj Group**
N (Total Vaccinated Cohort)	36	40	37	36	50	40	35	41	35
Females:Males	18:18	19:21	16:21	21:15	34:16	27:13	18:17	23:18	18:17
Mean Age, years (SD)	36.3 (12.80)	36.3 (12.36)	36.8 (12.87)	39.5 (13.27)	32.1 (9.96)	38.5 (13.43)	38.3 (14.61)	34.8 (14.57)	35.9 (12.78)
White - Caucasian / European heritage, n (%)	36 (100)	38 (95.0)	37 (100)	36 (100)	48 (96.0)	40 (100)	34 (97.1)	41 (100)	35 (100)
Month 24 Results									
Number of subjects	**H5N1/D1 Group**	**H5N1/D2 Group**	**H5N1/D3 Group**	**H5N1/D4 Group**	**Control Group**	**H5N1/D1/Adj Group**	**H5N1/D2/Adj Group**	**H5N1/D3/Adj Group**	**H5N1/D4/Adj Group**
Completed to Month 24, n (%)	33 (91.7)	37 (92.5)	31 (83.8)	34 (94.4)	40 (80.0)	38 (95.0)	33 (94.3)	36 (87.8)	30 (85.7)
Total Number Subjects Withdrawn, n (%)	1 (2.8)	2 (5.0)	4 (10.8)	2 (5.6)	9 (18.0)	2 (5.0)	2 (5.7)	3 (7.3)	3 (8.6)
Withdrawn due to Adverse Events, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.4)	1 (2.9)
Withdrawn due to Lack of Efficacy, n (%)	NA	NA	NA	NA	NA	NA	NA	NA	NA
Withdrawn for other reasons, n (%)	1 (2.8)	2 (5.0)	4 (10.8)	2 (5.6)	9 (18.0)	2 (5.0)	2 (5.7)	2 (4.9)	2 (5.7)
Demographics	**H5N1/D1 Group**	**H5N1/D2 Group**	**H5N1/D3 Group**	**H5N1/D4 Group**	**Control Group**	**H5N1/D1/Adj Group**	**H5N1/D2/Adj Group**	**H5N1/D3/Adj Group**	**H5N1/D4/Adj Group**
N (Total Vaccinated Cohort)	36	40	37	36	50	40	35	41	35
Females:Males	18:18	19:21	16:21	21:15	34:16	27:13	18:17	23:18	18:17
Mean Age, years (SD)	36.3 (12.80)	36.3 (12.36)	36.8 (12.87)	39.5 (13.27)	32.1 (9.96)	38.5 (13.43)	38.3 (14.61)	34.8 (14.57)	35.9 (12.78)
White - Caucasian / European heritage, n (%)	36 (100)	38 (95.0)	37 (100)	36 (100)	48 (96.0)	40 (100)	34 (97.1)	41 (100)	35 (100)
NA: Not applicable									
Primary Efficacy Results: GMTs and seropositivity rates of H5N1 haemagglutinin inhibition (HI) antibodies against the A/Indonesia/05/2005 strain at each time point in the H5N1 AD groups (ATP cohort for immunogenicity)									
Antibodies against	**Group**	**Timing**	**N**	**≥ 1:10**		**GMT**			

				N	%	95% CI		value	95% CI	
						LL	UL		LL	UL
A/Indonesia/05/2005	H5N1/D1/Adj	PRE*	39	1	2.6	0.1	13.5	5.1	4.9	5.3
		PI(D7)	38	33	86.8	71.9	95.6	169.0	94.5	302.2
		PI(D14)	39	36	92.3	79.1	98.4	448.8	253.4	795.0
		PI(D21)*	39	36	92.3	79.1	98.4	406.8	225.9	732.7
	H5N1/D2/Adj	PRE*	33	3	9.1	1.9	24.3	5.6	4.8	6.5
		PI(D7)	33	31	93.9	79.8	99.3	193.3	118.9	314.3
		PI(D14)	33	32	97.0	84.2	99.9	429.3	258.9	712.1
		PI(D21)*	33	33	100	89.4	100	429.5	281.2	655.9
	H5N1/D3/Adj	PRE*	38	2	5.3	0.6	17.7	5.3	4.9	5.8
		PI(D7)	38	32	84.2	68.7	94.0	118.5	69.3	202.5
		PI(D14)	38	33	86.8	71.9	95.6	206.5	118.3	360.6
		PI(D21)*	38	35	92.1	78.6	98.3	208.4	126.3	343.9
	H5N1/D4/Adj	PRE*	32	1	3.1	0.1	16.2	5.2	4.8	5.5
		PI(D7)	33	31	93.9	79.8	99.3	174.0	109.7	275.9
		PI(D14)	33	32	97.0	84.2	99.9	333.8	207.6	536.5
		PI(D21)*	33	32	97.0	84.2	99.9	347.9	213.6	566.8

N = Number of subjects with available results
n/% = number/percentage of seropositive subjects (HI titer ≥ 1:10)
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PRE = Pre-vaccination at Day 0
PI(D7) = Post-vaccination one at Day 7
PI(D14) = Post-vaccination one at Day 14
PI(D21) = Post-vaccination one at Day 21
* Primary Outcome Results

Primary Efficacy Results: SCR for H5N1 HI antibodies against the A/Indonesia/05/2005 strain at each post-vaccination time point in the H5N1 AD groups (ATP cohort for immunogenicity)

Antibodies against	**Group**	**Timing**	**N**	**SCR**			
				n	**%**	**95% CI**	
						LL	**UL**
A/Indonesia/05/2005	H5N1/D1/Adj	PI(D7)	38	32	84.2	68.7	94.0
		PI(D14)	39	36	92.3	79.1	98.4
		PI(D21)*	39	36	92.3	79.1	98.4
	H5N1/D2/Adj	PI(D7)	33	31	93.9	79.8	99.3
		PI(D14)	33	32	97.0	84.2	99.9
		PI(D21)*	33	33	100	89.4	100
	H5N1/D3/Adj	PI(D7)	38	32	84.2	68.7	94.0
		PI(D14)	38	33	86.8	71.9	95.6
		PI(D21)*	38	34	89.5	75.2	97.1
	H5N1/D4/Adj	PI(D7)	32	30	93.8	79.2	99.2
		PI(D14)	32	31	96.9	83.8	99.9
		PI(D21)*	32	31	96.9	83.8	99.9

Seroconversion defined as:
For initially seronegative subjects, antibody titer ≥ 1:40 after vaccination
For initially seropositive subjects, antibody titer after vaccination ≥ 4 fold the pre-vaccination antibody titer
N = Number of subjects with pre- and post-vaccination results available
n/% = Number/percentage of seroconverted subjects
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PI(D7) = Post-vaccination one at Day 7
PI(D14) = Post-vaccination one at Day 14
PI(D21) = Post-vaccination one at Day 21
* Primary Outcome Results

Primary Efficacy Results: SCF for H5N1 HI antibodies against the A/Indonesia/05/2005 strain at each post-vaccination time

point in the H5N1 AD groups (ATP cohort for immunogenicity)

Antibodies against	Group	Timing	N	SCF		
				Value	95% CI	
					LL	UL
A/Indonesia/05/2005	H5N1/D1/Adj	PI(D7)	38	33.2	18.6	59.3
		PI(D14)	39	88.2	49.9	155.8
		PI(D21)*	39	79.9	44.5	143.6
	H5N1/D2/Adj	PI(D7)	33	34.5	21.2	55.9
		PI(D14)	33	76.5	46.4	126.2
		PI(D21)*	33	76.5	50.7	115.6
	H5N1/D3/Adj	PI(D7)	38	22.2	13.3	37.0
		PI(D14)	38	38.8	22.8	66.0
		PI(D21)*	38	39.1	24.2	63.1
	H5N1/D4/Adj	PI(D7)	32	37.6	25.0	56.6
		PI(D14)	32	73.7	49.9	108.8
		PI(D21)*	32	76.9	51.5	115.0

N = Number of subjects with pre- and post-vaccination results available
SCF = Seroconversion Factor or geometric mean ratio (mean[log10(POST/PRE)])
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PI(D7) = Post-vaccination one at Day 7
PI(D14) = Post-vaccination one at Day 14
PI(D21) = Post-vaccination one at Day 21
* Primary Outcome Results

Primary Efficacy Results: SPR for H5N1 HI antibodies against the A/Indonesia/05/2005 strain at each post-vaccination time point in the H5N1 AD groups (ATP cohort for immunogenicity)

Antibodies against	Group	Timing	N	SPR			
				n	%	95% CI	
						LL	UL
A/Indonesia/05/2005	H5N1/D1/Adj	PRE*	39	0	0.0	0.0	9.0
		PI(D7)	38	32	84.2	68.7	94.0
		PI(D14)	39	36	92.3	79.1	98.4
		PI(D21)*	39	36	92.3	79.1	98.4
	H5N1/D2/Adj	PRE*	33	1	3.0	0.1	15.8
		PI(D7)	33	31	93.9	79.8	99.3
		PI(D14)	33	32	97.0	84.2	99.9
		PI(D21)*	33	33	100	89.4	100
	H5N1/D3/Adj	PRE*	38	0	0.0	0.0	9.3
		PI(D7)	38	32	84.2	68.7	94.0
		PI(D14)	38	33	86.8	71.9	95.6
		PI(D21)*	38	34	89.5	75.2	97.1
	H5N1/D4/Adj	PRE*	32	0	0.0	0.0	10.9
		PI(D7)	33	30	90.9	75.7	98.1
		PI(D14)	33	31	93.9	79.8	99.3
		PI(D21)*	33	31	93.9	79.8	99.3

N = Number of subjects with available results
n/% = Number/percentage of seroprotected subjects (HI titer $\geq$ 1:40)
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PRE = Pre-vaccination at Day 0
PI(D7) = Post-vaccination one at Day 7
PI(D14) = Post-vaccination one at Day 14
PI(D21) = Post-vaccination one at Day 21
* Primary Outcome Results

Primary Efficacy Results: Incidence of solicited local symptoms reported during the 7-day (Days 0-6) post-vaccination period following each dose and overall (Total Vaccinated Cohort)

Symptom	Intensity	H5N1/D1 Group					H5N1/D2 Group					H5N1/D3 Group				
		N	n	%	95% CI		N	n	%	95% CI		N	n	%	95% CI	
					LL	UL				LL	UL				LL	UL
Dose 1																
Ecchymosis	Any	36	0	0.0	0.0	9.7	40	0	0.0	0.0	8.8	36	0	0.0	0.0	9.7
(mm)	>100 mm	36	0	0.0	0.0	9.7	40	0	0.0	0.0	8.8	36	0	0.0	0.0	9.7
Induration	Any	36	5	13.9	4.7	29.5	40	1	2.5	0.1	13.2	36	3	8.3	1.8	22.5
(mm)	>100 mm	36	0	0.0	0.0	9.7	40	0	0.0	0.0	8.8	36	0	0.0	0.0	9.7
Pain	Any	36	33	91.7	77.5	98.2	40	35	87.5	73.2	95.8	36	32	88.9	73.9	96.9
	Grade 3	36	2	5.6	0.7	18.7	40	0	0.0	0.0	8.8	36	0	0.0	0.0	9.7
Redness	Any	36	0	0.0	0.0	9.7	40	1	2.5	0.1	13.2	36	0	0.0	0.0	9.7
(mm)	>100 mm	36	0	0.0	0.0	9.7	40	0	0.0	0.0	8.8	36	0	0.0	0.0	9.7
Swelling	Any	36	4	11.1	3.1	26.1	40	2	5.0	0.6	16.9	36	4	11.1	3.1	26.1
(mm)	>100 mm	36	0	0.0	0.0	9.7	40	0	0.0	0.0	8.8	36	0	0.0	0.0	9.7
Dose 2																
Ecchymosis	Any	35	0	0.0	0.0	10.0	40	0	0.0	0.0	8.8	36	0	0.0	0.0	9.7
(mm)	>100 mm	35	0	0.0	0.0	10.0	40	0	0.0	0.0	8.8	36	0	0.0	0.0	9.7
Induration	Any	35	1	2.9	0.1	14.9	40	5	12.5	4.2	26.8	36	3	8.3	1.8	22.5
(mm)	>100 mm	35	0	0.0	0.0	10.0	40	0	0.0	0.0	8.8	36	0	0.0	0.0	9.7
Pain	Any	35	28	80.0	63.1	91.6	40	30	75.0	58.8	87.3	36	24	66.7	49.0	81.4
	Grade 3	35	0	0.0	0.0	10.0	40	0	0.0	0.0	8.8	36	0	0.0	0.0	9.7
Redness	Any	35	0	0.0	0.0	10.0	40	1	2.5	0.1	13.2	36	0	0.0	0.0	9.7
(mm)	>100 mm	35	0	0.0	0.0	10.0	40	0	0.0	0.0	8.8	36	0	0.0	0.0	9.7
Swelling	Any	35	3	8.6	1.8	23.1	40	0	0.0	0.0	8.8	36	2	5.6	0.7	18.7
(mm)	>100 mm	35	0	0.0	0.0	10.0	40	0	0.0	0.0	8.8	36	0	0.0	0.0	9.7
Across doses																
Ecchymosis	Any	36	0	0.0	0.0	9.7	40	0	0.0	0.0	8.8	36	0	0.0	0.0	9.7
(mm)	>100 mm	36	0	0.0	0.0	9.7	40	0	0.0	0.0	8.8	36	0	0.0	0.0	9.7
Induration	Any	36	6	16.7	6.4	32.8	40	5	12.5	4.2	26.8	36	5	13.9	4.7	29.5
(mm)	>100 mm	36	0	0.0	0.0	9.7	40	0	0.0	0.0	8.8	36	0	0.0	0.0	9.7
Pain	Any	36	34	94.4	81.3	99.3	40	36	90.0	76.3	97.2	36	32	88.9	73.9	96.9
	Grade 3	36	2	5.6	0.7	18.7	40	0	0.0	0.0	8.8	36	0	0.0	0.0	9.7
Redness	Any	36	0	0.0	0.0	9.7	40	1	2.5	0.1	13.2	36	0	0.0	0.0	9.7
(mm)	>100 mm	36	0	0.0	0.0	9.7	40	0	0.0	0.0	8.8	36	0	0.0	0.0	9.7
Swelling	Any	36	5	13.9	4.7	29.5	40	2	5.0	0.6	16.9	36	5	13.9	4.7	29.5
(mm)	>100 mm	36	0	0.0	0.0	9.7	40	0	0.0	0.0	8.8	36	0	0.0	0.0	9.7

Symptom	Intensity	H5N1/D4 Group					Control Group				
		N	n	%	95% CI		N	n	%	95% CI	
					LL	UL				LL	UL
Dose 1											
Ecchymosis	Any	36	0	0.0	0.0	9.7	50	0	0.0	0.0	7.1
(mm)	>100 mm	36	0	0.0	0.0	9.7	50	0	0.0	0.0	7.1
Induration	Any	36	2	5.6	0.7	18.7	50	2	4.0	0.5	13.7
(mm)	>100 mm	36	0	0.0	0.0	9.7	50	0	0.0	0.0	7.1
Pain	Any	36	34	94.4	81.3	99.3	50	45	90.0	78.2	96.7
	Grade 3	36	2	5.6	0.7	18.7	50	1	2.0	0.1	10.6
Redness	Any	36	0	0.0	0.0	9.7	50	1	2.0	0.1	10.6
(mm)	>100 mm	36	0	0.0	0.0	9.7	50	0	0.0	0.0	7.1
Swelling	Any	36	4	11.1	3.1	26.1	50	3	6.0	1.3	16.5
(mm)	>100 mm	36	0	0.0	0.0	9.7	50	1	2.0	0.1	10.6
Dose 2											
Ecchymosis	Any	33	0	0.0	0.0	10.6	49	0	0.0	0.0	7.3
(mm)	>100 mm	33	0	0.0	0.0	10.6	49	0	0.0	0.0	7.3

Induration (mm)	Any	33	1	3.0	0.1	15.8	49	4	8.2	2.3	19.6
	>100 mm	33	0	0.0	0.0	10.6	49	0	0.0	0.0	7.3
Pain	Any	33	28	84.8	68.1	94.9	49	42	85.7	72.8	94.1
	Grade 3	33	0	0.0	0.0	10.6	49	2	4.1	0.5	14.0
Redness (mm)	Any	33	0	0.0	0.0	10.6	49	2	4.1	0.5	14.0
	>100 mm	33	0	0.0	0.0	10.6	49	0	0.0	0.0	7.3
Swelling (mm)	Any	33	5	15.2	5.1	31.9	49	5	10.2	3.4	22.2
	>100 mm	33	0	0.0	0.0	10.6	49	1	2.0	0.1	10.9
Across doses											
Ecchymosis (mm)	Any	36	0	0.0	0.0	9.7	50	0	0.0	0.0	7.1
	>100 mm	36	0	0.0	0.0	9.7	50	0	0.0	0.0	7.1
Induration (mm)	Any	36	2	5.6	0.7	18.7	50	6	12.0	4.5	24.3
	>100 mm	36	0	0.0	0.0	9.7	50	0	0.0	0.0	7.1
Pain	Any	36	35	97.2	85.5	99.9	50	47	94.0	83.5	98.7
	Grade 3	36	2	5.6	0.7	18.7	50	3	6.0	1.3	16.5
Redness (mm)	Any	36	0	0.0	0.0	9.7	50	3	6.0	1.3	16.5
	>100 mm	36	0	0.0	0.0	9.7	50	0	0.0	0.0	7.1
Swelling (mm)	Any	36	6	16.7	6.4	32.8	50	6	12.0	4.5	24.3
	>100 mm	36	0	0.0	0.0	9.7	50	1	2.0	0.1	10.6

Symptom	**Intensity**	**H5N1/D1/Adj Group**					**H5N1/D2/Adj Group**					**H5N1/D3/Adj Group**					**H5N1/D4/Adj Group**				
		N	**n**	**%**	**95% CI**		**N**	**n**	**%**	**95% CI**		**N**	**n**	**%**	**95% CI**		**N**	**n**	**%**	**95% CI**	
					LL	**UL**				**LL**	**UL**				**LL**	**UL**				**LL**	**UL**
Dose 1																					
Ecchymosis (mm)	Any	40	0	0.0	0.0	8.8	35	0	0.0	0.0	10.0	41	0	0.0	0.0	8.6	35	0	0.0	0.0	10.0
	>100 mm	40	0	0.0	0.0	8.8	35	0	0.0	0.0	10.0	41	0	0.0	0.0	8.6	35	0	0.0	0.0	10.0
Induration (mm)	Any	40	2	5.0	0.6	16.9	35	3	8.6	1.8	23.1	41	3	7.3	1.5	19.9	35	4	11.4	3.2	26.7
	>100 mm	40	0	0.0	0.0	8.8	35	0	0.0	0.0	10.0	41	0	0.0	0.0	8.6	35	0	0.0	0.0	10.0
Pain	Any	40	38	95.0	83.1	99.4	35	34	97.1	85.1	99.9	41	39	95.1	83.5	99.4	35	31	88.6	73.3	96.8
	Grade 3	40	1	2.5	0.1	13.2	35	1	2.9	0.1	14.9	41	1	2.4	0.1	12.9	35	0	0.0	0.0	10.0
Redness (mm)	Any	40	1	2.5	0.1	13.2	35	3	8.6	1.8	23.1	41	1	2.4	0.1	12.9	35	1	2.9	0.1	14.9
	>100 mm	40	0	0.0	0.0	8.8	35	0	0.0	0.0	10.0	41	0	0.0	0.0	8.6	35	0	0.0	0.0	10.0
Swelling (mm)	Any	40	2	5.0	0.6	16.9	35	2	5.7	0.7	19.2	41	3	7.3	1.5	19.9	35	2	5.7	0.7	19.2
	>100 mm	40	0	0.0	0.0	8.8	35	0	0.0	0.0	10.0	41	0	0.0	0.0	8.6	35	0	0.0	0.0	10.0
Dose 2																					
Ecchymosis (mm)	Any	-	-	-	-	-	1	0	0.0	0.0	97.5	1	0	0.0	0.0	97.5	1	0	0.0	0.0	97.5
	>100 mm	-	-	-	-	-	1	0	0.0	0.0	97.5	1	0	0.0	0.0	97.5	1	0	0.0	0.0	97.5
Induration (mm)	Any	-	-	-	-	-	1	1	100	2.5	100	1	0	0.0	0.0	97.5	1	0	0.0	0.0	97.5
	>100 mm	-	-	-	-	-	1	0	0.0	0.0	97.5	1	0	0.0	0.0	97.5	1	0	0.0	0.0	97.5
Pain	Any	-	-	-	-	-	1	1	100	2.5	100	1	1	100	2.5	100	1	1	100	2.5	100
	Grade 3	-	-	-	-	-	1	0	0.0	0.0	97.5	1	0	0.0	0.0	97.5	1	0	0.0	0.0	97.5
Redness (mm)	Any	-	-	-	-	-	1	1	100	2.5	100	1	0	0.0	0.0	97.5	1	0	0.0	0.0	97.5
	>100 mm	-	-	-	-	-	1	0	0.0	0.0	97.5	1	0	0.0	0.0	97.5	1	0	0.0	0.0	97.5
Swelling (mm)	Any	-	-	-	-	-	1	1	100	2.5	100	1	0	0.0	0.0	97.5	1	0	0.0	0.0	97.5
	>100 mm	-	-	-	-	-	1	0	0.0	0.0	97.5	1	0	0.0	0.0	97.5	1	0	0.0	0.0	97.5
Across doses																					
Ecchymosis (mm)	Any	40	0	0.0	0.0	8.8	35	0	0.0	0.0	10.0	41	0	0.0	0.0	8.6	35	0	0.0	0.0	10.0
	>100 mm	40	0	0.0	0.0	8.8	35	0	0.0	0.0	10.0	41	0	0.0	0.0	8.6	35	0	0.0	0.0	10.0
Induration (mm)	Any	40	2	5.0	0.6	16.9	35	4	11.4	3.2	26.7	41	3	7.3	1.5	19.9	35	4	11.4	3.2	26.7
	>100 mm	40	0	0.0	0.0	8.8	35	0	0.0	0.0	10.0	41	0	0.0	0.0	8.6	35	0	0.0	0.0	10.0
Pain	Any	40	38	95.0	83.1	99.4	35	34	97.1	85.1	99.9	41	39	95.1	83.5	99.4	35	31	88.6	73.3	96.8
	Grade 3	40	1	2.5	0.1	13.2	35	1	2.9	0.1	14.9	41	1	2.4	0.1	12.9	35	0	0.0	0.0	10.0
Redness (mm)	Any	40	1	2.5	0.1	13.2	35	4	11.4	3.2	26.7	41	1	2.4	0.1	12.9	35	1	2.9	0.1	14.9
	>100 mm	40	0	0.0	0.0	8.8	35	0	0.0	0.0	10.0	41	0	0.0	0.0	8.6	35	0	0.0	0.0	10.0

Swelling (mm)	Any	40	2	5.0	0.6	16.9	35	3	8.6	1.8	23.1	41	3	7.3	1.5	19.9	35	2	5.7	0.7	19.2
	>100 mm	40	0	0.0	0.0	8.8	35	0	0.0	0.0	10.0	41	0	0.0	0.0	8.6	35	0	0.0	0.0	10.0

N= number of subjects with at least one documented dose
n/%= number/percentage of subjects reporting at least once the symptom
Any= occurrence of any local symptom regardless of intensity grade
Grade 3 pain= pain that prevented normal activity
95% CI= Exact 95% confidence interval; LL = lower limit, UL = upper limit

Primary Efficacy Results: Incidence of solicited general symptoms reported during the 7-day (Days 0-6) post-vaccination period following each dose and overall (Total Vaccinated Cohort)

Symptom	**Intensity/ Relationship**	**H5N1/D1 Group**					**H5N1/D2 Group**					**H5N1/D3 Group**				
		N	**n**	**%**	**95% CI**		**N**	**n**	**%**	**95% CI**		**N**	**n**	**%**	**95% CI**	
					LL	**UL**				**LL**	**UL**				**LL**	**UL**
Dose 1																
Arthralgia	Any	36	5	13.9	4.7	29.5	40	7	17.5	7.3	32.8	36	2	5.6	0.7	18.7
	Grade 3	36	1	2.8	0.1	14.5	40	0	0.0	0.0	8.8	36	0	0.0	0.0	9.7
	Related	36	4	11.1	3.1	26.1	40	5	12.5	4.2	26.8	36	2	5.6	0.7	18.7
Fatigue	Any	36	12	33.3	18.6	51.0	40	15	37.5	22.7	54.2	36	15	41.7	25.5	59.2
	Grade 3	36	1	2.8	0.1	14.5	40	0	0.0	0.0	8.8	36	0	0.0	0.0	9.7
	Related	36	10	27.8	14.2	45.2	40	12	30.0	16.6	46.5	36	15	41.7	25.5	59.2
Fever (Axillary)(°C)	≥ 38.0	36	0	0.0	0.0	9.7	40	0	0.0	0.0	8.8	36	0	0.0	0.0	9.7
	≥ 39.0	36	0	0.0	0.0	9.7	40	0	0.0	0.0	8.8	36	0	0.0	0.0	9.7
	Related	36	0	0.0	0.0	9.7	40	0	0.0	0.0	8.8	36	0	0.0	0.0	9.7
Headache	Any	36	14	38.9	23.1	56.5	40	15	37.5	22.7	54.2	36	12	33.3	18.6	51.0
	Grade 3	36	0	0.0	0.0	9.7	40	0	0.0	0.0	8.8	36	0	0.0	0.0	9.7
	Related	36	11	30.6	16.3	48.1	40	11	27.5	14.6	43.9	36	11	30.6	16.3	48.1
Myalgia	Any	36	12	33.3	18.6	51.0	40	17	42.5	27.0	59.1	36	14	38.9	23.1	56.5
	Grade 3	36	2	5.6	0.7	18.7	40	0	0.0	0.0	8.8	36	0	0.0	0.0	9.7
	Related	36	12	33.3	18.6	51.0	40	15	37.5	22.7	54.2	36	14	38.9	23.1	56.5
Shivering	Any	36	4	11.1	3.1	26.1	40	1	2.5	0.1	13.2	36	1	2.8	0.1	14.5
	Grade 3	36	1	2.8	0.1	14.5	40	0	0.0	0.0	8.8	36	0	0.0	0.0	9.7
	Related	36	4	11.1	3.1	26.1	40	1	2.5	0.1	13.2	36	1	2.8	0.1	14.5
Sweating	Any	36	2	5.6	0.7	18.7	40	4	10.0	2.8	23.7	36	6	16.7	6.4	32.8
	Grade 3	36	1	2.8	0.1	14.5	40	0	0.0	0.0	8.8	36	0	0.0	0.0	9.7
	Related	36	2	5.6	0.7	18.7	40	2	5.0	0.6	16.9	36	6	16.7	6.4	32.8
Dose 2																
Arthralgia	Any	35	9	25.7	12.5	43.3	40	4	10.0	2.8	23.7	36	5	13.9	4.7	29.5
	Grade 3	35	1	2.9	0.1	14.9	40	0	0.0	0.0	8.8	36	0	0.0	0.0	9.7
	Related	35	6	17.1	6.6	33.6	40	4	10.0	2.8	23.7	36	5	13.9	4.7	29.5
Fatigue	Any	35	13	37.1	21.5	55.1	40	12	30.0	16.6	46.5	36	9	25.0	12.1	42.2
	Grade 3	35	1	2.9	0.1	14.9	40	0	0.0	0.0	8.8	36	0	0.0	0.0	9.7
	Related	35	12	34.3	19.1	52.2	40	10	25.0	12.7	41.2	36	6	16.7	6.4	32.8
Fever (Axillary)(°C)	≥ 38.0	35	1	2.9	0.1	14.9	40	1	2.5	0.1	13.2	36	0	0.0	0.0	9.7
	≥ 39.0	35	0	0.0	0.0	10.0	40	0	0.0	0.0	8.8	36	0	0.0	0.0	9.7
	Related	35	1	2.9	0.1	14.9	40	1	2.5	0.1	13.2	36	0	0.0	0.0	9.7
Headache	Any	35	14	40.0	23.9	57.9	40	10	25.0	12.7	41.2	36	12	33.3	18.6	51.0
	Grade 3	35	0	0.0	0.0	10.0	40	0	0.0	0.0	8.8	36	0	0.0	0.0	9.7
	Related	35	12	34.3	19.1	52.2	40	9	22.5	10.8	38.5	36	8	22.2	10.1	39.2
Myalgia	Any	35	11	31.4	16.9	49.3	40	9	22.5	10.8	38.5	36	9	25.0	12.1	42.2
	Grade 3	35	1	2.9	0.1	14.9	40	0	0.0	0.0	8.8	36	0	0.0	0.0	9.7
	Related	35	11	31.4	16.9	49.3	40	8	20.0	9.1	35.6	36	9	25.0	12.1	42.2
Shivering	Any	35	7	20.0	8.4	36.9	40	3	7.5	1.6	20.4	36	4	11.1	3.1	26.1
	Grade 3	35	0	0.0	0.0	10.0	40	0	0.0	0.0	8.8	36	0	0.0	0.0	9.7
	Related	35	6	17.1	6.6	33.6	40	3	7.5	1.6	20.4	36	4	11.1	3.1	26.1

Sweating	Any	35	7	20.0	8.4	36.9	40	2	5.0	0.6	16.9	36	3	8.3	1.8	22.5
	Grade 3	35	0	0.0	0.0	10.0	40	0	0.0	0.0	8.8	36	0	0.0	0.0	9.7
	Related	35	5	14.3	4.8	30.3	40	2	5.0	0.6	16.9	36	3	8.3	1.8	22.5
Across Doses																
Arthralgia	Any	36	13	36.1	20.8	53.8	40	8	20.0	9.1	35.6	36	6	16.7	6.4	32.8
	Grade 3	36	2	5.6	0.7	18.7	40	0	0.0	0.0	8.8	36	0	0.0	0.0	9.7
	Related	36	10	27.8	14.2	45.2	40	6	15.0	5.7	29.8	36	6	16.7	6.4	32.8
Fatigue	Any	36	20	55.6	38.1	72.1	40	21	52.5	36.1	68.5	36	17	47.2	30.4	64.5
	Grade 3	36	2	5.6	0.7	18.7	40	0	0.0	0.0	8.8	36	0	0.0	0.0	9.7
	Related	36	17	47.2	30.4	64.5	40	18	45.0	29.3	61.5	36	17	47.2	30.4	64.5
Fever (Axillary)(°C)	≥ 38.0	36	1	2.8	0.1	14.5	40	1	2.5	0.1	13.2	36	0	0.0	0.0	9.7
	≥ 39.0	36	0	0.0	0.0	9.7	40	0	0.0	0.0	8.8	36	0	0.0	0.0	9.7
	Related	36	1	2.8	0.1	14.5	40	1	2.5	0.1	13.2	36	0	0.0	0.0	9.7
Headache	Any	36	20	55.6	38.1	72.1	40	17	42.5	27.0	59.1	36	17	47.2	30.4	64.5
	Grade 3	36	0	0.0	0.0	9.7	40	0	0.0	0.0	8.8	36	0	0.0	0.0	9.7
	Related	36	18	50.0	32.9	67.1	40	16	40.0	24.9	56.7	36	14	38.9	23.1	56.5
Myalgia	Any	36	17	47.2	30.4	64.5	40	20	50.0	33.8	66.2	36	15	41.7	25.5	59.2
	Grade 3	36	3	8.3	1.8	22.5	40	0	0.0	0.0	8.8	36	0	0.0	0.0	9.7
	Related	36	17	47.2	30.4	64.5	40	18	45.0	29.3	61.5	36	15	41.7	25.5	59.2
Shivering	Any	36	10	27.8	14.2	45.2	40	3	7.5	1.6	20.4	36	4	11.1	3.1	26.1
	Grade 3	36	1	2.8	0.1	14.5	40	0	0.0	0.0	8.8	36	0	0.0	0.0	9.7
	Related	36	9	25.0	12.1	42.2	40	3	7.5	1.6	20.4	36	4	11.1	3.1	26.1
Sweating	Any	36	9	25.0	12.1	42.2	40	4	10.0	2.8	23.7	36	6	16.7	6.4	32.8
	Grade 3	36	1	2.8	0.1	14.5	40	0	0.0	0.0	8.8	36	0	0.0	0.0	9.7
	Related	36	7	19.4	8.2	36.0	40	3	7.5	1.6	20.4	36	6	16.7	6.4	32.8

Symptom	**Intensity/ Relationship**	**H5N1/D4 Group**					**Control Group**				
		N	**n**	**%**	**95% CI**		**N**	**n**	**%**	**95% CI**	
					LL	**UL**				**LL**	**UL**
Dose 1											
Arthralgia	Any	36	5	13.9	4.7	29.5	50	9	18.0	8.6	31.4
	Grade 3	36	1	2.8	0.1	14.5	50	2	4.0	0.5	13.7
	Related	36	5	13.9	4.7	29.5	50	7	14.0	5.8	26.7
Fatigue	Any	36	15	41.7	25.5	59.2	50	24	48.0	33.7	62.6
	Grade 3	36	0	0.0	0.0	9.7	50	2	4.0	0.5	13.7
	Related	36	13	36.1	20.8	53.8	50	22	44.0	30.0	58.7
Fever (Axillary)(°C)	≥ 38.0	36	0	0.0	0.0	9.7	50	0	0.0	0.0	7.1
	≥ 39.0	36	0	0.0	0.0	9.7	50	0	0.0	0.0	7.1
	Related	36	0	0.0	0.0	9.7	50	0	0.0	0.0	7.1
Headache	Any	36	11	30.6	16.3	48.1	50	14	28.0	16.2	42.5
	Grade 3	36	0	0.0	0.0	9.7	50	3	6.0	1.3	16.5
	Related	36	10	27.8	14.2	45.2	50	11	22.0	11.5	36.0
Myalgia	Any	36	12	33.3	18.6	51.0	50	18	36.0	22.9	50.8
	Grade 3	36	1	2.8	0.1	14.5	50	2	4.0	0.5	13.7
	Related	36	10	27.8	14.2	45.2	50	17	34.0	21.2	48.8
Shivering	Any	36	5	13.9	4.7	29.5	50	7	14.0	5.8	26.7
	Grade 3	36	1	2.8	0.1	14.5	50	2	4.0	0.5	13.7
	Related	36	4	11.1	3.1	26.1	50	6	12.0	4.5	24.3
Sweating	Any	36	3	8.3	1.8	22.5	50	10	20.0	10.0	33.7
	Grade 3	36	0	0.0	0.0	9.7	50	0	0.0	0.0	7.1
	Related	36	2	5.6	0.7	18.7	50	6	12.0	4.5	24.3
Dose 2											
Arthralgia	Any	33	6	18.2	7.0	35.5	49	10	20.4	10.2	34.3
	Grade 3	33	0	0.0	0.0	10.6	49	0	0.0	0.0	7.3

	Related	33	6	18.2	7.0	35.5	49	10	20.4	10.2	34.3
Fatigue	Any	33	13	39.4	22.9	57.9	49	25	51.0	36.3	65.6
	Grade 3	33	0	0.0	0.0	10.6	49	3	6.1	1.3	16.9
	Related	33	13	39.4	22.9	57.9	49	24	49.0	34.4	63.7
Fever (Axillary)(°C)	≥ 38.0	33	0	0.0	0.0	10.6	49	4	8.2	2.3	19.6
	≥ 39.0	33	0	0.0	0.0	10.6	49	0	0.0	0.0	7.3
	Related	33	0	0.0	0.0	10.6	49	4	8.2	2.3	19.6
Headache	Any	33	9	27.3	13.3	45.5	49	23	46.9	32.5	61.7
	Grade 3	33	0	0.0	0.0	10.6	49	3	6.1	1.3	16.9
	Related	33	9	27.3	13.3	45.5	49	19	38.8	25.2	53.8
Myalgia	Any	33	7	21.2	9.0	38.9	49	24	49.0	34.4	63.7
	Grade 3	33	0	0.0	0.0	10.6	49	0	0.0	0.0	7.3
	Related	33	6	18.2	7.0	35.5	49	22	44.9	30.7	59.8
Shivering	Any	33	3	9.1	1.9	24.3	49	14	28.6	16.6	43.3
	Grade 3	33	0	0.0	0.0	10.6	49	1	2.0	0.1	10.9
	Related	33	3	9.1	1.9	24.3	49	14	28.6	16.6	43.3
Sweating	Any	33	2	6.1	0.7	20.2	49	10	20.4	10.2	34.3
	Grade 3	33	0	0.0	0.0	10.6	49	1	2.0	0.1	10.9
	Related	33	2	6.1	0.7	20.2	49	10	20.4	10.2	34.3
Across doses											
Arthralgia	Any	36	10	27.8	14.2	45.2	50	14	28.0	16.2	42.5
	Grade 3	36	1	2.8	0.1	14.5	50	2	4.0	0.5	13.7
	Related	36	10	27.8	14.2	45.2	50	13	26.0	14.6	40.3
Fatigue	Any	36	20	55.6	38.1	72.1	50	30	60.0	45.2	73.6
	Grade 3	36	0	0.0	0.0	9.7	50	5	10.0	3.3	21.8
	Related	36	20	55.6	38.1	72.1	50	29	58.0	43.2	71.8
Fever (Axillary)(°C)	≥ 38.0	36	0	0.0	0.0	9.7	50	4	8.0	2.2	19.2
	≥ 39.0	36	0	0.0	0.0	9.7	50	0	0.0	0.0	7.1
	Related	36	0	0.0	0.0	9.7	50	4	8.0	2.2	19.2
Headache	Any	36	14	38.9	23.1	56.5	50	28	56.0	41.3	70.0
	Grade 3	36	0	0.0	0.0	9.7	50	4	8.0	2.2	19.2
	Related	36	14	38.9	23.1	56.5	50	22	44.0	30.0	58.7
Myalgia	Any	36	15	41.7	25.5	59.2	50	30	60.0	45.2	73.6
	Grade 3	36	1	2.8	0.1	14.5	50	2	4.0	0.5	13.7
	Related	36	14	38.9	23.1	56.5	50	28	56.0	41.3	70.0
Shivering	Any	36	7	19.4	8.2	36.0	50	20	40.0	26.4	54.8
	Grade 3	36	1	2.8	0.1	14.5	50	3	6.0	1.3	16.5
	Related	36	7	19.4	8.2	36.0	50	19	38.0	24.7	52.8
Sweating	Any	36	5	13.9	4.7	29.5	50	13	26.0	14.6	40.3
	Grade 3	36	0	0.0	0.0	9.7	50	1	2.0	0.1	10.6
	Related	36	4	11.1	3.1	26.1	50	12	24.0	13.1	38.2

Symptom	**Intensity/ Relationship**	**H5N1/D1/Adj Group**					**H5N1/D2/Adj Group**					**H5N1/D3/Adj Group**					**H5N1/D4/Adj Group**				
		N	**n**	**%**	**95% CI**		**N**	**n**	**%**	**95% CI**		**N**	**n**	**%**	**95% CI**		**N**	**n**	**%**	**95% CI**	
					LL	**UL**				**LL**	**UL**				**LL**	**UL**				**LL**	**UL**
Dose 1																					
Arthralgia	Any	40	6	15.0	5.7	29.8	35	5	14.3	4.8	30.3	41	5	12.2	4.1	26.2	35	5	14.3	4.8	30.3
	Grade 3	40	0	0.0	0.0	8.8	35	0	0.0	0.0	10.0	41	0	0.0	0.0	8.6	35	0	0.0	0.0	10.0
	Related	40	5	12.5	4.2	26.8	35	5	14.3	4.8	30.3	41	5	12.2	4.1	26.2	35	4	11.4	3.2	26.7
Fatigue	Any	40	15	37.5	22.7	54.2	35	10	28.6	14.6	46.3	41	18	43.9	28.5	60.3	35	13	37.1	21.5	55.1
	Grade 3	40	1	2.5	0.1	13.2	35	0	0.0	0.0	10.0	41	1	2.4	0.1	12.9	35	0	0.0	0.0	10.0
	Related	40	15	37.5	22.7	54.2	35	9	25.7	12.5	43.3	41	17	41.5	26.3	57.9	35	12	34.3	19.1	52.2
Fever (Axillary)	≥ 38.0	40	0	0.0	0.0	8.8	35	0	0.0	0.0	10.0	41	0	0.0	0.0	8.6	35	0	0.0	0.0	10.0
	≥ 39.0	40	0	0.0	0.0	8.8	35	0	0.0	0.0	10.0	41	0	0.0	0.0	8.6	35	0	0.0	0.0	10.0

(°C)	Related	40	0	0.0	0.0	8.8	35	0	0.0	0.0	10.0	41	0	0.0	0.0	8.6	35	0	0.0	0.0	10.0
Headache	Any	40	19	47.5	31.5	63.9	35	10	28.6	14.6	46.3	41	11	26.8	14.2	42.9	35	9	25.7	12.5	43.3
	Grade 3	40	0	0.0	0.0	8.8	35	0	0.0	0.0	10.0	41	1	2.4	0.1	12.9	35	0	0.0	0.0	10.0
	Related	40	16	40.0	24.9	56.7	35	9	25.7	12.5	43.3	41	10	24.4	12.4	40.3	35	8	22.9	10.4	40.1
Myalgia	Any	40	12	30.0	16.6	46.5	35	12	34.3	19.1	52.2	41	11	26.8	14.2	42.9	35	10	28.6	14.6	46.3
	Grade 3	40	0	0.0	0.0	8.8	35	0	0.0	0.0	10.0	41	2	4.9	0.6	16.5	35	0	0.0	0.0	10.0
	Related	40	11	27.5	14.6	43.9	35	11	31.4	16.9	49.3	41	9	22.0	10.6	37.6	35	9	25.7	12.5	43.3
Shivering	Any	40	9	22.5	10.8	38.5	35	6	17.1	6.6	33.6	41	6	14.6	5.6	29.2	35	3	8.6	1.8	23.1
	Grade 3	40	0	0.0	0.0	8.8	35	0	0.0	0.0	10.0	41	0	0.0	0.0	8.6	35	0	0.0	0.0	10.0
	Related	40	9	22.5	10.8	38.5	35	6	17.1	6.6	33.6	41	5	12.2	4.1	26.2	35	3	8.6	1.8	23.1
Sweating	Any	40	5	12.5	4.2	26.8	35	6	17.1	6.6	33.6	41	4	9.8	2.7	23.1	35	3	8.6	1.8	23.1
	Grade 3	40	1	2.5	0.1	13.2	35	0	0.0	0.0	10.0	41	0	0.0	0.0	8.6	35	0	0.0	0.0	10.0
	Related	40	5	12.5	4.2	26.8	35	6	17.1	6.6	33.6	41	3	7.3	1.5	19.9	35	3	8.6	1.8	23.1
Dose 2																					
Arthralgia	Any	-	-	-	-	-	1	0	0.0	0.0	97.5	1	0	0.0	0.0	97.5	1	0	0.0	0.0	97.5
	Grade 3	-	-	-	-	-	1	0	0.0	0.0	97.5	1	0	0.0	0.0	97.5	1	0	0.0	0.0	97.5
	Related	-	-	-	-	-	1	0	0.0	0.0	97.5	1	0	0.0	0.0	97.5	1	0	0.0	0.0	97.5
Fatigue	Any	-	-	-	-	-	1	0	0.0	0.0	97.5	1	1	100	2.5	100	1	0	0.0	0.0	97.5
	Grade 3	-	-	-	-	-	1	0	0.0	0.0	97.5	1	0	0.0	0.0	97.5	1	0	0.0	0.0	97.5
	Related	-	-	-	-	-	1	0	0.0	0.0	97.5	1	1	100	2.5	100	1	0	0.0	0.0	97.5
Fever (Axillary) (°C)	≥ 38.0	-	-	-	-	-	1	0	0.0	0.0	97.5	1	0	0.0	0.0	97.5	1	0	0.0	0.0	97.5
	≥ 39.0	-	-	-	-	-	1	0	0.0	0.0	97.5	1	0	0.0	0.0	97.5	1	0	0.0	0.0	97.5
	Related	-	-	-	-	-	1	0	0.0	0.0	97.5	1	0	0.0	0.0	97.5	1	0	0.0	0.0	97.5
Headache	Any	-	-	-	-	-	1	0	0.0	0.0	97.5	1	1	100	2.5	100	1	0	0.0	0.0	97.5
	Grade 3	-	-	-	-	-	1	0	0.0	0.0	97.5	1	0	0.0	0.0	97.5	1	0	0.0	0.0	97.5
	Related	-	-	-	-	-	1	0	0.0	0.0	97.5	1	1	100	2.5	100	1	0	0.0	0.0	97.5
Myalgia	Any	-	-	-	-	-	1	0	0.0	0.0	97.5	1	1	100	2.5	100	1	0	0.0	0.0	97.5
	Grade 3	-	-	-	-	-	1	0	0.0	0.0	97.5	1	0	0.0	0.0	97.5	1	0	0.0	0.0	97.5
	Related	-	-	-	-	-	1	0	0.0	0.0	97.5	1	1	100	2.5	100	1	0	0.0	0.0	97.5
Shivering	Any	-	-	-	-	-	1	0	0.0	0.0	97.5	1	1	100	2.5	100	1	0	0.0	0.0	97.5
	Grade 3	-	-	-	-	-	1	0	0.0	0.0	97.5	1	0	0.0	0.0	97.5	1	0	0.0	0.0	97.5
	Related	-	-	-	-	-	1	0	0.0	0.0	97.5	1	1	100	2.5	100	1	0	0.0	0.0	97.5
Sweating	Any	-	-	-	-	-	1	0	0.0	0.0	97.5	1	1	100	2.5	100	1	0	0.0	0.0	97.5
	Grade 3	-	-	-	-	-	1	0	0.0	0.0	97.5	1	0	0.0	0.0	97.5	1	0	0.0	0.0	97.5
	Related	-	-	-	-	-	1	0	0.0	0.0	97.5	1	1	100	2.5	100	1	0	0.0	0.0	97.5
Across doses																					
Arthralgia	Any	40	6	15.0	5.7	29.8	35	5	14.3	4.8	30.3	41	5	12.2	4.1	26.2	35	5	14.3	4.8	30.3
	Grade 3	40	0	0.0	0.0	8.8	35	0	0.0	0.0	10.0	41	0	0.0	0.0	8.6	35	0	0.0	0.0	10.0
	Related	40	5	12.5	4.2	26.8	35	5	14.3	4.8	30.3	41	5	12.2	4.1	26.2	35	4	11.4	3.2	26.7
Fatigue	Any	40	15	37.5	22.7	54.2	35	10	28.6	14.6	46.3	41	18	43.9	28.5	60.3	35	13	37.1	21.5	55.1
	Grade 3	40	1	2.5	0.1	13.2	35	0	0.0	0.0	10.0	41	1	2.4	0.1	12.9	35	0	0.0	0.0	10.0
	Related	40	15	37.5	22.7	54.2	35	9	25.7	12.5	43.3	41	17	41.5	26.3	57.9	35	12	34.3	19.1	52.2
Fever (Axillary) (°C)	≥ 38.0	40	0	0.0	0.0	8.8	35	0	0.0	0.0	10.0	41	0	0.0	0.0	8.6	35	0	0.0	0.0	10.0
	≥ 39.0	40	0	0.0	0.0	8.8	35	0	0.0	0.0	10.0	41	0	0.0	0.0	8.6	35	0	0.0	0.0	10.0
	Related	40	0	0.0	0.0	8.8	35	0	0.0	0.0	10.0	41	0	0.0	0.0	8.6	35	0	0.0	0.0	10.0
Headache	Any	40	19	47.5	31.5	63.9	35	10	28.6	14.6	46.3	41	11	26.8	14.2	42.9	35	9	25.7	12.5	43.3
	Grade 3	40	0	0.0	0.0	8.8	35	0	0.0	0.0	10.0	41	1	2.4	0.1	12.9	35	0	0.0	0.0	10.0
	Related	40	16	40.0	24.9	56.7	35	9	25.7	12.5	43.3	41	10	24.4	12.4	40.3	35	8	22.9	10.4	40.1
Myalgia	Any	40	12	30.0	16.6	46.5	35	12	34.3	19.1	52.2	41	11	26.8	14.2	42.9	35	10	28.6	14.6	46.3
	Grade 3	40	0	0.0	0.0	8.8	35	0	0.0	0.0	10.0	41	2	4.9	0.6	16.5	35	0	0.0	0.0	10.0
	Related	40	11	27.5	14.6	43.9	35	11	31.4	16.9	49.3	41	9	22.0	10.6	37.6	35	9	25.7	12.5	43.3
Shivering	Any	40	9	22.5	10.8	38.5	35	6	17.1	6.6	33.6	41	6	14.6	5.6	29.2	35	3	8.6	1.8	23.1
	Grade 3	40	0	0.0	0.0	8.8	35	0	0.0	0.0	10.0	41	0	0.0	0.0	8.6	35	0	0.0	0.0	10.0

	Related	40	9	22.5	10.8	38.5	35	6	17.1	6.6	33.6	41	5	12.2	4.1	26.2	35	3	8.6	1.8	23.1
Sweating	Any	40	5	12.5	4.2	26.8	35	6	17.1	6.6	33.6	41	4	9.8	2.7	23.1	35	3	8.6	1.8	23.1
	Grade 3	40	1	2.5	0.1	13.2	35	0	0.0	0.0	10.0	41	0	0.0	0.0	8.6	35	0	0.0	0.0	10.0
	Related	40	5	12.5	4.2	26.8	35	6	17.1	6.6	33.6	41	3	7.3	1.5	19.9	35	3	8.6	1.8	23.1

N= number of subjects with at least one documented dose
n/%= number/percentage of subjects reporting at least once the symptom
Any= occurrence of any solicited general symptom regardless of their intensity grade or relationship to vaccination
Grade 3 symptoms = symptoms that prevented normal activity
Related= general symptom assessed by the investigator as causally related to the study vaccination
95% CI= Exact 95% confidence interval; LL = lower limit, UL = upper limit

Primary Efficacy Results: Please refer to the safety section for the results of unsolicited symptoms and SAEs.

Secondary Outcome Variable(s): Seropositivity rates and GMTs of H5N1 HI antibodies against the A/Indonesia/05/2005 strain at each time point in the H5N1 non-AD and Control groups (ATP cohort for immunogenicity)

Antibodies against	**Group**	**Timing**	**N**	**≥ 1:10**				**GMT**		
				n	**%**	**95% CI**		**value**	**95% CI**	
						LL	**UL**		**LL**	**UL**
A/Indonesia/05/2005	H5N1/D1	PRE	34	1	2.9	0.1	15.3	5.1	4.9	5.3
		PI(D7)	34	17	50.0	32.4	67.6	22.1	11.7	41.8
		PI(D14)	34	22	64.7	46.5	80.3	46.6	24.0	90.7
		PI(D21)	34	22	64.7	46.5	80.3	38.0	20.4	70.6
		PII(D28)	34	25	73.5	55.6	87.1	48.1	26.1	88.7
		PII(D35)	33	23	69.7	51.3	84.4	56.0	28.6	109.8
		PII(D42)	34	23	67.6	49.5	82.6	54.3	27.9	105.8
	H5N1/D2	PRE	38	0	0.0	0.0	9.3	5.0	5.0	5.0
		PI(D7)	38	22	57.9	40.8	73.7	25.3	14.5	44.4
		PI(D14)	38	31	81.6	65.7	92.3	66.1	39.7	109.9
		PI(D21)	38	32	84.2	68.7	94.0	57.6	36.9	90.0
		PII(D28)	38	35	92.1	78.6	98.3	79.3	52.7	119.3
		PII(D35)	36	33	91.7	77.5	98.2	119.9	77.5	185.5
		PII(D42)	38	35	92.1	78.6	98.3	116.3	77.2	175.4
	H5N1/D3	PRE	33	0	0.0	0.0	10.6	5.0	5.0	5.0
		PI(D7)	33	20	60.6	42.1	77.1	27.7	16.1	47.6
		PI(D14)	32	22	68.8	50.0	83.9	49.1	25.7	93.8
		PI(D21)	32	22	68.8	50.0	83.9	42.2	23.0	77.4
		PII(D28)	32	24	75.0	56.6	88.5	56.0	31.2	100.4
		PII(D35)	32	25	78.1	60.0	90.7	65.8	36.1	120.2
		PII(D42)	32	24	75.0	56.6	88.5	63.7	34.5	117.9
	H5N1/D4	PRE	28	0	0.0	0.0	12.3	5.0	5.0	5.0
		PI(D7)	28	18	64.3	44.1	81.4	37.6	19.3	73.4
		PI(D14)	28	23	82.1	63.1	93.9	71.5	39.0	131.2
		PI(D21)	28	24	85.7	67.3	96.0	77.1	45.1	131.7
		PII(D28)	28	27	96.4	81.7	99.9	128.0	81.8	200.4
		PII(D35)	28	27	96.4	81.7	99.9	160.0	100.8	254.2
		PII(D42)	28	27	96.4	81.7	99.9	141.4	92.3	216.7
	Control	PRE	49	0	0.0	0.0	7.3	5.0	5.0	5.0
		PI(D7)	49	0	0.0	0.0	7.3	5.0	5.0	5.0
		PI(D14)	49	23	46.9	32.5	61.7	13.7	9.6	19.5
		PI(D21)	49	35	71.4	56.7	83.4	31.0	20.8	46.3
		PII(D28)	49	49	100	92.7	100	543.9	423.3	698.8
		PII(D35)	49	49	100	92.7	100	563.6	438.5	724.4
		PII(D42)	49	49	100	92.7	100	443.0	335.6	584.7

N = Number of subjects with available results
n/% = number/percentage of seropositive subjects (HI titer ≥ 1:10)

95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PRE = Pre-vaccination at Day 0
PI(D7) = Post-vaccination one at Day 7
PI(D14) = Post-vaccination one at Day 14
PI(D21) = Post-vaccination one at Day 21
PII(D28) = Post-vaccination two at Day 28
PII(D35) = Post-vaccination two at Day 35
PII(D42) = Post-vaccination two at Day 42

Secondary Outcome Variable(s): Seropositivity rates and GMTs of H5N1 HI antibodies against A/Indonesia/05/2005 strain at Day 0 and Month 6 (ATP cohort for persistence)

Antibodies against	Group	Timing	N	≥ 1:10				GMT		
				n	%	95% CI		value	95% CI	
						LL	UL		LL	UL
A/Indonesia/05/2005	H5N1/D1	PRE	35	1	2.9	0.1	14.9	5.1	4.9	5.3
		PII(M6)	35	19	54.3	36.6	71.2	17.6	10.9	28.4
	H5N1/D2	PRE	40	1	2.5	0.1	13.2	5.3	4.7	5.9
		PII(M6)	40	26	65.0	48.3	79.4	17.6	11.6	26.6
	H5N1/D3	PRE	36	0	0.0	0.0	9.7	5.0	5.0	5.0
		PII(M6)	36	21	58.3	40.8	74.5	18.5	12.1	28.5
	H5N1/D4	PRE	35	0	0.0	0.0	10.0	5.0	5.0	5.0
		PII(M6)	35	27	77.1	59.9	89.6	24.3	16.5	35.9
	Control	PRE	46	0	0.0	0.0	7.7	5.0	5.0	5.0
		PII(M6)	46	27	58.7	43.2	73.0	17.8	12.3	25.9
	H5N1/D1/Adj	PRE	38	1	2.6	0.1	13.8	5.1	4.9	5.3
		PI(M6)	39	29	74.4	57.9	87.0	81.5	43.4	153.0
	H5N1/D2/Adj	PRE	32	3	9.4	2.0	25.0	5.6	4.8	6.5
		PI(M6)	33	29	87.9	71.8	96.6	82.5	47.7	142.7
	H5N1/D3/Adj	PRE	40	2	5.0	0.6	16.9	5.3	4.9	5.8
		PI(M6)	40	29	72.5	56.1	85.4	42.1	24.9	71.0
	H5N1/D4/Adj	PRE	32	1	3.1	0.1	16.2	5.2	4.8	5.5
		PI(M6)	33	25	75.8	57.7	88.9	47.3	27.5	81.5

N = Number of subjects with available results
n/% = number/percentage of seropositive subjects (HI titer ≥ 1:10)
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PRE = Pre-vaccination at Day 0
PI(M6)= Post-vaccination one at Month 6
PII(M6)= Post-vaccination two at Month 6

Secondary Outcome Variable(s): Seropositivity rates and GMTs of H5N1 HI antibodies against A/Indonesia/05/2005 strain at Day 0 and Month 12 (ATP cohort for persistence)

Antibodies against	Group	Timing	N	≥ 1:10				GMT		
				n	%	95% CI			95% CI	
						LL	UL	value	LL	UL
A/Indonesia/05/2005	H5N1/D1	PRE	32	1	3.1	0.1	16.2	5.1	4.9	5.3
		PII(M12)	32	18	56.3	37.7	73.6	19.6	11.7	32.8
	H5N1/D2	PRE	39	1	2.6	0.1	13.5	5.3	4.7	5.9
		PII(M12)	39	22	56.4	39.6	72.2	17.5	11.3	27.2
	H5N1/D3	PRE	36	0	0.0	0.0	9.7	5.0	5.0	5.0
		PII(M12)	36	24	66.7	49.0	81.4	22.4	15.0	33.7
	H5N1/D4	PRE	33	0	0.0	0.0	10.6	5.0	5.0	5.0
		PII(M12)	33	23	69.7	51.3	84.4	19.0	12.8	28.2
	Control	PRE	44	0	0.0	0.0	8.0	5.0	5.0	5.0
		PII(M12)	44	23	52.3	36.7	67.5	16.2	10.9	23.9
	H5N1/D1/Adj	PRE	36	1	2.8	0.1	14.5	5.1	4.9	5.3

		PI(M12)	37	30	81.1	64.8	92.0	100.2	53.5	187.6
	H5N1/D2/Adj	PRE	29	3	10.3	2.2	27.4	5.7	4.8	6.7
		PI(M12)	30	27	90.0	73.5	97.9	108.0	61.1	190.9
	H5N1/D3/Adj	PRE	39	2	5.1	0.6	17.3	5.3	4.9	5.8
		PI(M12)	39	30	76.9	60.7	88.9	59.7	34.8	102.3
	H5N1/D4/Adj	PRE	31	1	3.2	0.1	16.7	5.2	4.8	5.5
		PI(M12)	31	26	83.9	66.3	94.5	64.7	37.9	110.5

N = Number of subjects with available results
n/% = number/percentage of seropositive subjects (HI titer ≥ 1:10)
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PRE = Pre-vaccination at Day 0
PI(M12) = Post-vaccination one at month 12
PII(M12)= Post-vaccination two at month 12

Secondary Outcome Variable(s): Seropositivity rates and GMTs of H5N1 HI antibodies against A/Indonesia/05/2005 strain at Day 0 and Month 18 (ATP cohort for persistence)

Antibodies against	**Group**	**Timing**	**N**	**≥ 1:10**				**GMT**		
				n	**%**	**95% CI**		**value**	**95% CI**	
						LL	**UL**		**LL**	**UL**
A/Indonesia/05/2005	H5N1/D1	PRE	32	1	3.1	0.1	16.2	5.1	4.9	5.3
		PII(M18)	31	15	48.4	30.2	66.9	13.1	8.2	20.8
	H5N1/D2	PRE	38	1	2.6	0.1	13.8	5.3	4.7	5.9
		PII(M18)	36	25	69.4	51.9	83.7	22.9	15.3	34.3
	H5N1/D3	PRE	34	0	0.0	0.0	10.3	5.0	5.0	5.0
		PII(M18)	29	18	62.1	42.3	79.3	20.5	13.0	32.3
	H5N1/D4	PRE	32	0	0.0	0.0	10.9	5.0	5.0	5.0
		PII(M18)	30	24	80.0	61.4	92.3	33.3	22.1	50.3
	Control	PRE	44	0	0.0	0.0	8.0	5.0	5.0	5.0
		PII(M18)	37	18	48.6	31.9	65.6	12.0	8.1	18.0
	H5N1/D1/Adj	PRE	35	1	2.9	0.1	14.9	5.1	4.9	5.3
		PI(M18)	34	24	70.6	52.5	84.9	55.4	28.4	108.4
	H5N1/D2/Adj	PRE	29	3	10.3	2.2	27.4	5.7	4.8	6.7
		PI(M18)	29	24	82.8	64.2	94.2	65.3	36.0	118.3
	H5N1/D3/Adj	PRE	39	2	5.1	0.6	17.3	5.3	4.9	5.8
		PI(M18)	34	27	79.4	62.1	91.3	42.5	25.7	70.4
	H5N1/D4/Adj	PRE	30	1	3.3	0.1	17.2	5.2	4.8	5.6
		PI(M18)	29	24	82.8	64.2	94.2	55.3	31.2	98.1

GMT = Geometric Mean antibody Titer
N = Number of subjects with available results
n/% = number/percentage of seropositive subjects (HI titer ≥ 1:10)
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PRE = Pre-vaccination at Day 0
PI(M18) = Post-vaccination one at Month 18
PII(M18) = Post-vaccination two at Month 18

Secondary Outcome Variable(s): Seropositivity rates and GMTs of H5N1 HI antibodies against A/Indonesia/05/2005 strain at Month 18 and Month 24 (ATP cohort for persistence at Month 24)

Antibodies against	**Group**	**Timing**	**N**	**≥ 1:10**				**GMT**		
				n	**%**	**95% CI**		**value**	**95% CI**	
						LL	**UL**		**LL**	**UL**
A/Indonesia/05/2005	H5N1/D1	PII(M24)	30	10	33.3	17.3	52.8	9.9	6.6	14.9
	H5N1/D2	PII(M24)	36	13	36.1	20.8	53.8	9.0	6.7	12.0
	H5N1/D3	PII(M24)	29	10	34.5	17.9	54.3	9.4	6.5	13.6
	H5N1/D4	PII(M24)	27	10	37.0	19.4	57.6	8.7	6.4	11.8
	Control	PII(M24)	32	14	43.8	26.4	62.3	10.9	7.4	16.1
	H5N1/D1/Adj	PI(M24)	34	21	61.8	43.6	77.8	38.0	20.1	71.8

	H5N1/D2/Adj	PI(M24)	28	18	64.3	44.1	81.4	31.2	16.9	57.7
	H5N1/D3/Adj	PI(M24)	35	19	54.3	36.6	71.2	21.9	12.7	37.5
	H5N1/D4/Adj	PI(M24)	26	17	65.4	44.3	82.8	22.9	12.9	40.4

N = Number of subjects with available results
n/% = number/percentage of seropositive subjects (HI titer ≥ 1:10)
PII(M18) = Post-vaccination two at Month 18
PII(M24)= Post-vaccination two at Month 24

Secondary Outcome Variable(s): Seropositivity rates and GMTs of H5N1 neutralizing antibodies against the A/Indonesia/05/2005 strain at Days 0, 21 and 42 in the H5N1/D1, H5N1/D1/Adj and Control groups (ATP cohort for immunogenicity)

Antibodies against	Group	Timing	N	≥ 1:28				GMT		
				n	%	95% CI		value	95% CI	
						LL	UL		LL	UL
A/Indonesia/05/2005	H5N1/D1	PRE	34	25	73.5	55.6	87.1	47.0	34.2	64.6
		PI(D21)	34	34	100	89.7	100	692.4	476.7	1005.7
		PII(D42)	34	34	100	89.7	100	933.1	653.7	1331.9
	H5N1/D1/Adj	PRE	38	38	100	90.7	100	157.8	130.3	191.2
		PI(D21)	38	38	100	90.7	100	3708.9	2458.6	5594.9
	Control	PRE	49	10	20.4	10.2	34.3	19.9	15.7	25.2
		PI(D21)	49	49	100	92.7	100	307.3	262.5	359.8
		PII(D42)	49	49	100	92.7	100	1606.4	1282.7	2011.8

N = Number of subjects with available results
n/% = number/percentage of seropositive subjects (HI titer ≥ 1:28)
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PRE = Pre-vaccination at Day 0
PI(D21) = Post-vaccination one at Day 21
PII(D42) = Post-vaccination two at Day 42

Secondary Outcome Variable(s): Seropositivity rates and GMTs of neutralizing antibody titers against the A/Indonesia/05/2005 vaccine strain at Day 0 and Month 6 (ATP cohort for persistence)

Antibodies against	Group	Timing	N	≥ 1:28				GMT		
				n	%	95% CI		value	95% CI	
						LL	UL		LL	UL
A/Indonesia/05/2005	H5N1/D1/Adj	PRE	37	37	100	90.5	100	155.4	127.9	188.7
		PI(M6)	37	37	100	90.5	100	1422.2	916.8	2206.2
	H5N1/D1	PRE	35	27	77.1	59.9	89.6	50.8	37.4	69.0
		PII(M6)	35	35	100	90.0	100	502.3	349.2	722.5
	Control	PRE	46	9	19.6	9.4	33.9	19.7	15.4	25.3
		PII(M6)	46	46	100	92.3	100	751.3	611.4	923.3

N = Number of subjects with pre- and post-vaccination results available
n/% = number/percentage of seropositive subjects (NEUTRA titer ≥ 1:28)
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PRE = Pre-vaccination at Day 0
PI(M6) = Post-vaccination one at month 6
PII(M6) = Post-vaccination two at month 6

Secondary Outcome Variable(s): Seropositivity rates and GMTs for neutralizing antibody titers against A/Indonesia/05/2005 strain at Day 0 and Month 12 (ATP cohort for persistence)

Antibodies against	Group	Timing	N	≥ 1:28				GMT		
				n	%	95% CI		value	95% CI	
						LL	UL		LL	UL
A/Indonesia/05/2005	H5N1/D1/Adj	PRE	36	35	97.2	85.5	99.9	144.2	113.3	183.4
		PI(M12)	37	35	94.6	81.8	99.3	557.6	354.0	878.4
	H5N1/D1	PRE	32	26	81.3	63.6	92.8	55.7	40.7	76.1
		PII(M12)	32	32	100	89.1	100	180.7	121.3	269.2
	Control	PRE	44	9	20.5	9.8	35.3	20.1	15.5	26.0

		PII(M12)	44	44	100	92.0	100	274.4	215.7	349.1

N = Number of subjects with available results
n/% = number/percentage of seropositive subjects (NEUTRA titer ≥ 1:28)
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PRE = Pre-vaccination at Day 0
PI(M12) = Post-vaccination one at month 12
PII(M12) = Post-vaccination two at month 12

Secondary Outcome Variable(s): Seropositivity rates and GMTs of neutralizing antibody titers against A/Indonesia/05/2005 strain at Day 0 and Month 18 (ATP cohort for persistence)

Antibodies against	Group	Timing	N	≥ 1:28				GMT		
				n	%	95% CI		value	95% CI	
						LL	UL		LL	UL
A/Indonesia/05/2005	H5N1/D1/Adj	PRE	35	34	97.1	85.1	99.9	140.4	110.3	178.9
		PI(M18)	34	33	97.1	84.7	99.9	767.5	494.8	1190.6
	H5N1/D1	PRE	32	26	81.3	63.6	92.8	55.7	40.7	76.1
		PII(M18)	31	29	93.5	78.6	99.2	278.5	173.7	446.5
	Control	PRE	44	9	20.5	9.8	35.3	20.1	15.5	26.0
		PII(M18)	37	37	100	90.5	100	569.9	442.9	733.4

GMT = Geometric Mean antibody Titer
N = Number of subjects with available results
n/% = number/percentage of seropositive subjects (NEUTRA titer ≥ 1:28)
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PRE = Pre-vaccination at Day 0
PI(M18) = Post-vaccination one at Month 18
PII(M18) = Post-vaccination two at Month 18

Secondary Outcome Variable(s): Seropositivity rates and GMTs of neutralizing antibody titers against A/Indonesia/05/2005 strain at Month 18 and Month 24 (ATP cohort for persistence)

Antibodies against	Group	Timing	N	≥ 28 1/DIL				GMT		
				n	%	95% CI		value	95% CI	
						LL	UL		LL	UL
A/Indonesia/05/2005	H5N1/D1/Adj	PI(M24)	34	33	97.1	84.7	99.9	503.2	338.3	748.4
	H5N1/D1	PII(M24)	30	29	96.7	82.8	99.9	201.6	143.2	283.8
	Control	PII(M24)	32	32	100	89.1	100	295.4	237.8	367.0

N = Number of subjects with available results
n/% = number/percentage of seropositive subjects (NEUTRA titer ≥ 1:28)
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PI(M18) = Post-vaccination one at Month 18
PII(M24) = Post-vaccination two at Month 24

Secondary Outcome Variable(s): SCR for H5N1 HI antibodies against the A/Indonesia/05/2005 strain at each post-vaccination time point in the H5N1 non-AD and Control groups (ATP cohort for immunogenicity)

Antibodies against	Group	Timing	N	SCR			
				n	%	95% CI	
						LL	UL
A/Indonesia/05/2005	H5N1/D1	PI(D7)	34	12	35.3	19.7	53.5
		PI(D14)	34	22	64.7	46.5	80.3
		PI(D21)	34	19	55.9	37.9	72.8
		PII(D35)	33	21	63.6	45.1	79.6
		PII(D42)	34	22	64.7	46.5	80.3
	H5N1/D2	PI(D7)	38	17	44.7	28.6	61.7
		PI(D14)	38	28	73.7	56.9	86.6
		PI(D21)	38	27	71.1	54.1	84.6
		PII(D35)	36	33	91.7	77.5	98.2
		PII(D42)	38	34	89.5	75.2	97.1
	H5N1/D3	PI(D7)	33	18	54.5	36.4	71.9

		PI(D14)	32	19	59.4	40.6	76.3
		PI(D21)	32	19	59.4	40.6	76.3
		PII(D35)	32	23	71.9	53.3	86.3
		PII(D42)	32	23	71.9	53.3	86.3
	H5N1/D4	PI(D7)	28	17	60.7	40.6	78.5
		PI(D14)	28	21	75.0	55.1	89.3
		PI(D21)	28	23	82.1	63.1	93.9
		PII(D35)	28	27	96.4	81.7	99.9
		PII(D42)	28	27	96.4	81.7	99.9
	Control	PI(D7)	49	0	0.0	0.0	7.3
		PI(D14)	49	12	24.5	13.3	38.9
		PI(D21)	49	29	59.2	44.2	73.0
		PII(D35)	49	49	100	92.7	100
		PII(D42)	49	48	98.0	89.1	99.9

Seroconversion defined as:
For initially seronegative subjects, antibody titer ≥ 1:40 after vaccination
For initially seropositive subjects, antibody titer after vaccination ≥ 4 fold the pre-vaccination antibody titer
N = Number of subjects with pre- and post-vaccination results available
n/% = Number/percentage of seroconverted subjects
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PI(D7) = Post-vaccination one at Day 7
PI(D14) = Post-vaccination one at Day 14
PI(D21) = Post-vaccination one at Day 21
PII(D35) = Post-vaccination two at Day 35
PII(D42) = Post-vaccination two at Day 42

Secondary Outcome Variable(s): SCR for H5N1 HI antibodies against A/Indonesia/05/2005 strain at Month 6 (ATP cohort for persistence)

Antibodies against	**Group**	**Timing**	**N**	**SCR**			
				n	**%**	**95% CI**	
						LL	**UL**
A/Indonesia/05/2005	H5N1/D1	PII(M6)	35	12	34.3	19.1	52.2
	H5N1/D2	PII(M6)	40	12	30.0	16.6	46.5
	H5N1/D3	PII(M6)	36	15	41.7	25.5	59.2
	H5N1/D4	PII(M6)	35	14	40.0	23.9	57.9
	Control	PII(M6)	46	15	32.6	19.5	48.0
	H5N1/D1/Adj	PI(M6)	38	26	68.4	51.3	82.5
	H5N1/D2/Adj	PI(M6)	32	24	75.0	56.6	88.5
	H5N1/D3/Adj	PI(M6)	40	20	50.0	33.8	66.2
	H5N1/D4/Adj	PI(M6)	32	24	75.0	56.6	88.5

Seroconversion defined as:
For initially seronegative subjects, antibody titer ≥ 1:40 after vaccination
For initially seropositive subjects, antibody titer after vaccination ≥ 4 fold the pre-vaccination antibody titer
N = Number of subjects with pre- and post-vaccination results available
n/% = Number/percentage of seroconverted subjects
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PI(M6)= Post-vaccination one at Month 6
PII(M6)= Post-vaccination two at Month 6

Secondary Outcome Variable(s): SCR for H5N1 HI antibody titers against A/Indonesia/05/2005 at Month 12 (ATP cohort for persistence)

Antibodies against	**Group**	**Timing**	**N**	**SCR**			
				n	**%**	**95% CI**	
						LL	**UL**
A/Indonesia/05/2005	H5N1/D1	PII(M12)	32	12	37.5	21.1	56.3
	H5N1/D2	PII(M12)	39	13	33.3	19.1	50.2

	H5N1/D3	PII(M12)	36	17	47.2	30.4	64.5
	H5N1/D4	PII(M12)	33	13	39.4	22.9	57.9
	Control	PII(M12)	44	16	36.4	22.4	52.2
	H5N1/D1/Adj	PI(M12)	36	27	75.0	57.8	87.9
	H5N1/D2/Adj	PI(M12)	29	24	82.8	64.2	94.2
	H5N1/D3/Adj	PI(M12)	39	27	69.2	52.4	83.0
	H5N1/D4/Adj	PI(M12)	30	23	76.7	57.7	90.1

Seroconversion defined as:
For initially seronegative subjects, antibody titer ≥ 1:40 after vaccination
For initially seropositive subjects, antibody titer after vaccination ≥ 4 fold the pre-vaccination antibody titer
N = Number of subjects with pre- and post-vaccination results available
n/% = Number/percentage of seroconverted subjects
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PI(M12) = Post-vaccination one at month 12
PII(M12) = Post-vaccination two at month 12

Secondary Outcome Variable(s): SCR for HI antibody titer against A/Indonesia/05/2005 strain at Month 18 (ATP cohort for persistence)

Antibodies against	Group	Timing	N	SCR			
				n	%	95% CI	
						LL	UL
A/Indonesia/05/2005	H5N1/D1	PII(M18)	31	8	25.8	11.9	44.6
	H5N1/D2	PII(M18)	36	17	47.2	30.4	64.5
	H5N1/D3	PII(M18)	29	15	51.7	32.5	70.6
	H5N1/D4	PII(M18)	30	19	63.3	43.9	80.1
	Control	PII(M18)	37	5	13.5	4.5	28.8
	H5N1/D1/Adj	PI(M18)	33	21	63.6	45.1	79.6
	H5N1/D2/Adj	PI(M18)	29	20	69.0	49.2	84.7
	H5N1/D3/Adj	PI(M18)	34	22	64.7	46.5	80.3
	H5N1/D4/Adj	PI(M18)	28	21	75.0	55.1	89.3

Seroconversion defined as:
For initially seronegative subjects, antibody titer ≥ 1:40 after vaccination
For initially seropositive subjects, antibody titer after vaccination ≥ 4 fold the pre-vaccination antibody titer
N = Number of subjects with pre- and post-vaccination results available
n/% = Number/percentage of seroconverted subjects
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PI(M18) = Post-vaccination one at Month 18
PII(M18) = Post-vaccination two at Month 18

Secondary Outcome Variable(s): SCR for HI antibodies against A/Indonesia/05/2005 at Month 18 and Month 24 (ATP cohort for persistence)

Antibodies against	Group	Timing	N	n	SCR		
					%	95% CI	
						LL	UL
A/Indonesia/05/2005	H5N1/D1	PII(M24)	30	7	23.3	9.9	42.3
	H5N1/D2	PII(M24)	36	5	13.9	4.7	29.5
	H5N1/D3	PII(M24)	29	7	24.1	10.3	43.5
	H5N1/D4	PII(M24)	27	3	11.1	2.4	29.2
	Control	PII(M24)	32	5	15.6	5.3	32.8
	H5N1/D1/Adj	PI(M24)	33	18	54.5	36.4	71.9
	H5N1/D2/Adj	PI(M24)	28	16	57.1	37.2	75.5
	H5N1/D3/Adj	PI(M24)	35	16	45.7	28.8	63.4
	H5N1/D4/Adj	PI(M24)	25	11	44.0	24.4	65.1

Seroconversion defined as:
For initially seronegative subjects, antibody titer ≥ 1:40 after vaccination
For initially seropositive subjects, antibody titer after vaccination ≥ 4 fold the pre-vaccination antibody titer

N = Number of subjects with pre- and post-vaccination results available
n/% = Number/percentage of seroconverted subjects
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PII(M18) = Post-vaccination two at Month 18
PII(M24)= Post-vaccination two at Month 24

Secondary Outcome Variable(s): SCR for H5N1 neutralizing antibodies against the A/Indonesia/05/2005 strain at Day 21 and Day 42 in the H5N1/D1, H5N1/D1/Adj and Control groups (ATP cohort for immunogenicity)

Antibodies against	Group	Timing	N	SCR			
				n	%	95% CI	
						LL	UL
A/Indonesia/05/2005	H5N1/D1	PI(D21)	34	29	85.3	68.9	95.0
		PII(D42)	34	31	91.2	76.3	98.1
	H5N1/D1/Adj	PI(D21)	38	35	92.1	78.6	98.3
	Control	PI(D21)	49	44	89.8	77.8	96.6
		PII(D42)	49	49	100	92.7	100

Seroconversion defined as:
For initially seronegative subjects, antibody titer $\geq$ 1:56 after vaccination
For initially seropositive subjects, antibody titer after vaccination $\geq$ 4 fold the pre-vaccination antibody titer
N = Number of subjects with pre- and post-vaccination results available
n/% = Number/percentage of seroconverted subjects
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PI(D21) = Post-vaccination one at Day 21
PII(D42) = Post-vaccination two at Day 42

Secondary Outcome Variable(s): SCR for neutralizing antibody titer at Month 6 against the A/Indonesia/05/2005 vaccine strain (ATP cohort for persistence)

Antibodies against	Group	Timing	N	SCR			
				n	%	95% CI	
						LL	UL
A/Indonesia/05/2005	H5N1/D1/Adj	PI(M6)	37	29	78.4	61.8	90.2
	H5N1/D1	PII(M6)	35	29	82.9	66.4	93.4
	Control	PII(M6)	46	44	95.7	85.2	99.5

Seroconversion defined as:
For initially seronegative subjects, antibody titer $\geq$ 1:56 after vaccination
For initially seropositive subjects, antibody titer after vaccination $\geq$ 4 fold the pre-vaccination antibody titer
N = Number of subjects with pre- and post-vaccination results available
n/% = Number/percentage of seroconverted subjects
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PRE = Pre-vaccination at Day 0
PI(M6) = Post-vaccination one at month 6
PII(M6) = Post-vaccination two at month 6

Secondary Outcome Variable(s): SCR for neutralizing antibody titer against A/Indonesia/05/2005 strain at Month 12 (ATP cohort for persistence)

Antibodies against	Group	Timing	N	SCR			
				n	%	95% CI	
						LL	UL
A/Indonesia/05/2005	H5N1/D1/Adj	PI(M12)	36	17	47.2	30.4	64.5
	H5N1/D1	PII(M12)	32	14	43.8	26.4	62.3
	Control	PII(M12)	44	41	93.2	81.3	98.6

Seroconversion defined as:
For initially seronegative subjects, antibody titer ≥ 1:56 after vaccination
For initially seropositive subjects, antibody titer after vaccination ≥ 4 fold the pre-vaccination antibody titer
N = Number of subjects with pre- and post-vaccination results available
n/% = Number/percentage of seroconverted subjects
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit

PI(M12) = Post-vaccination one at month 12
PII(M12) = Post-vaccination two at month 12

Secondary Outcome Variable(s): SCR for neutralizing antibody titer against A/Indonesia/05/2005 strain at Month 18 (ATP cohort for persistence)

Antibodies against	Group	Timing	N	SCR			
				n	%	95% CI	
						LL	UL
A/Indonesia/05/2005	H5N1/D1/Adj	PI(M18)	33	21	63.6	45.1	79.6
	H5N1/D1	PII(M18)	31	19	61.3	42.2	78.2
	Control	PII(M18)	37	35	94.6	81.8	99.3

Seroconversion defined as:
For initially seronegative subjects, antibody titer ≥ 1:56 after vaccination
For initially seropositive subjects, antibody titer after vaccination ≥ 4 fold the pre-vaccination antibody titer
N = Number of subjects with pre- and post-vaccination results available
n/% = Number/percentage of seroconverted subjects
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PI(M18) = Post-vaccination one at Month 18
PII(M18) = Post-vaccination two at Month 18

Secondary Outcome Variable(s): SCR for neutralizing antibody titer against A/Indonesia/05/2005 strain at Month 18 and Month 24 (ATP cohort for persistence)

Antibodies against	Group	Timing	N	SCR			
						95% CI	
				n	%	LL	UL
A/Indonesia/05/2005	H5N1/D1/Adj	PI(M24)	33	13	39.4	22.9	57.9
	H5N1/D1	PII(M24)	30	13	43.3	25.5	62.6
	Control	PII(M24)	32	29	90.6	75.0	98.0

Seroconversion defined as: antibody titer after vaccination ≥ 4 fold the pre-vaccination antibody titer
N = Number of subjects with pre- and post-vaccination results available
n/% = Number/percentage of seroconverted subjects
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PI(M18) = Post-vaccination one at month 18
PII(M24) = Post-vaccination two at month 24

Secondary Outcome Variable(s): SCF for H5N1 HI antibodies against the A/Indonesia/05/2005 strain at each post-vaccination time point in the H5N1 non-AD and Control groups (ATP cohort for immunogenicity)

Antibodies against	Group	Timing	N	SCF		
				Value	95% CI	
					LL	UL
A/Indonesia/05/2005	H5N1/D1	PI(D7)	34	4.3	2.3	8.2
		PI(D14)	34	9.1	4.7	17.7
		PI(D21)	34	7.4	4.0	13.8
		PII(D35)	33	11.0	5.6	21.4
		PII(D42)	34	10.6	5.5	20.7
	H5N1/D2	PI(D7)	38	5.1	2.9	8.9
		PI(D14)	38	13.2	7.9	22.0
		PI(D21)	38	11.5	7.4	18.0
		PII(D35)	36	24.0	15.5	37.1
		PII(D42)	38	23.3	15.4	35.1
	H5N1/D3	PI(D7)	33	5.5	3.2	9.5
		PI(D14)	32	9.8	5.1	18.8
		PI(D21)	32	8.4	4.6	15.5
		PII(D35)	32	13.2	7.2	24.0
		PII(D42)	32	12.7	6.9	23.6
	H5N1/D4	PI(D7)	28	7.5	3.9	14.7
		PI(D14)	28	14.3	7.8	26.2

		PI(D21)	28	15.4	9.0	26.3
		PII(D35)	28	32.0	20.2	50.8
		PII(D42)	28	28.3	18.5	43.3
	Control	PI(D7)	49	1.0	1.0	1.0
		PI(D14)	49	2.7	1.9	3.9
		PI(D21)	49	6.2	4.2	9.3
		PII(D35)	49	112.7	87.7	144.9
		PII(D42)	49	88.6	67.1	116.9

N = Number of subjects with pre- and post-vaccination results available
SCF = Seroconversion Factor or geometric mean ratio (mean[log10(POST/PRE)])
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PRE = Pre-vaccination at Day 0
PI(D7) = Post-vaccination one at Day 7
PI(D14) = Post-vaccination one at Day 14
PI(D21) = Post-vaccination one at Day 21
PII(D35) = Post-vaccination two at Day 35
PII(D42) = Post-vaccination two at Day 42

Secondary Outcome Variable(s): SCF for H5N1 HI antibodies against A/Indonesia/05/2005 strain at Month 6 (ATP cohort for persistence)

Antibodies against	Group	Timing	N	SCF		
				Value	95% CI	
					LL	UL
A/Indonesia/05/2005	H5N1/D1	PII(M6)	35	3.4	2.1	5.5
	H5N1/D2	PII(M6)	40	3.3	2.3	4.8
	H5N1/D3	PII(M6)	36	3.7	2.4	5.7
	H5N1/D4	PII(M6)	35	4.9	3.3	7.2
	Control	PII(M6)	46	3.6	2.5	5.2
	H5N1/D1/Adj	PI(M6)	38	15.0	8.0	28.2
	H5N1/D2/Adj	PI(M6)	32	14.1	8.1	24.2
	H5N1/D3/Adj	PI(M6)	40	7.9	4.8	13.1
	H5N1/D4/Adj	PI(M6)	32	9.8	5.8	16.7

N = Number of subjects with pre- and post-vaccination results available
SCF = Seroconversion Factor or geometric mean ratio (mean[log10(POST/PRE)])
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PI(M6)= Post-vaccination one at Month 6
PII(M6)= Post-vaccination two at Month 6

Secondary Outcome Variable(s): SCF for H5N1 HI antibody titers against A/Indonesia/05/2005 at Month 12 (ATP cohort for persistence)

Antibodies against	Group	Timing	N	SCF		
				Value	95% CI	
					LL	UL
A/Indonesia/05/2005	H5N1/D1	PII(M12)	32	3.8	2.3	6.4
	H5N1/D2	PII(M12)	39	3.3	2.2	4.9
	H5N1/D3	PII(M12)	36	4.5	3.0	6.7
	H5N1/D4	PII(M12)	33	3.8	2.6	5.6
	Control	PII(M12)	44	3.2	2.2	4.8
	H5N1/D1/Adj	PI(M12)	36	18.3	9.8	34.2
	H5N1/D2/Adj	PI(M12)	29	18.3	10.4	32.1
	H5N1/D3/Adj	PI(M12)	39	11.2	6.7	18.9
	H5N1/D4/Adj	PI(M12)	30	13.6	8.1	22.8

N = Number of subjects with pre- and post-vaccination results available
SCF = Seroconversion Factor or geometric mean ratio (mean[log10(POST/PRE)])
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PI(M12) = Post-vaccination one at month 12

PII(M12) = Post-vaccination two at month 12

Secondary Outcome Variable(s): SCF for HI antibody titer against A/Indonesia/05/2005 strain at Month 18 (ATP cohort for persistence)

Antibodies against	Group	Timing	N	SCF		
				Value	95% CI	
					LL	UL
A/Indonesia/05/2005	H5N1/D1	PII(M18)	31	2.6	1.6	4.0
	H5N1/D2	PII(M18)	36	4.6	3.1	6.9
	H5N1/D3	PII(M18)	29	4.1	2.6	6.5
	H5N1/D4	PII(M18)	30	6.7	4.4	10.1
	Control	PII(M18)	37	2.4	1.6	3.6
	H5N1/D1/Adj	PI(M18)	33	10.1	5.2	19.7
	H5N1/D2/Adj	PI(M18)	29	11.5	6.5	20.3
	H5N1/D3/Adj	PI(M18)	34	7.9	4.9	12.8
	H5N1/D4/Adj	PI(M18)	28	11.6	6.7	20.2

N = Number of subjects with pre- and post-vaccination results available
SCF = Seroconversion Factor or geometric mean ratio (mean[log10(POST/PRE)])
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PI(M18) = Post-vaccination one at Month 18
PII(M18) = Post-vaccination two at Month 18

Secondary Outcome Variable(s): SCF for HI antibodies against A/Indonesia/05/2005 at Month 18 and Month 24 (ATP cohort for persistence)

Antibodies against	Group	Timing	N	SCF		
				Value	95% CI	
					LL	UL
A/Indonesia/05/2005	H5N1/D1	PII(M24)	30	1.9	1.3	2.9
	H5N1/D2	PII(M24)	36	1.8	1.3	2.4
	H5N1/D3	PII(M24)	29	1.9	1.3	2.7
	H5N1/D4	PII(M24)	27	1.7	1.3	2.4
	Control	PII(M24)	32	2.2	1.5	3.2
	H5N1/D1/Adj	PI(M24)	33	6.9	3.7	13.0
	H5N1/D2/Adj	PI(M24)	28	5.9	3.2	10.7
	H5N1/D3/Adj	PI(M24)	35	4.1	2.4	6.8
	H5N1/D4/Adj	PI(M24)	25	4.7	2.6	8.3

N = Number of subjects with pre- and post-vaccination results available
SCF = Seroconversion Factor or geometric mean ratio (mean[log10(POST/PRE)])
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PII(M18) = Post-vaccination two at Month 18
PII(M24)= Post-vaccination two at Month 24

Secondary Outcome Variable(s): SPR for H5N1 HI antibodies against the A/Indonesia/05/2005 strain at each time point in the H5N1 non-AD and Control groups (ATP cohort for immunogenicity)

Antibodies against	Group	Timing	N	SPR			
				n	%	95% CI	
						LL	UL
A/Indonesia/05/2005	H5N1/D1	PRE	34	0	0.0	0.0	10.3
		PI(D7)	34	12	35.3	19.7	53.5
		PI(D14)	34	22	64.7	46.5	80.3
		PI(D21)	34	19	55.9	37.9	72.8
		PII(D28)	34	22	64.7	46.5	80.3
		PII(D35)	33	21	63.6	45.1	79.6
		PII(D42)	34	22	64.7	46.5	80.3
	H5N1/D2	PRE	38	0	0.0	0.0	9.3
		PI(D7)	38	17	44.7	28.6	61.7
		PI(D14)	38	28	73.7	56.9	86.6

		PI(D21)	38	27	71.1	54.1	84.6
		PII(D28)	38	32	84.2	68.7	94.0
		PII(D35)	36	33	91.7	77.5	98.2
		PII(D42)	38	34	89.5	75.2	97.1
	H5N1/D3	PRE	33	0	0.0	0.0	10.6
		PI(D7)	33	18	54.5	36.4	71.9
		PI(D14)	32	19	59.4	40.6	76.3
		PI(D21)	32	19	59.4	40.6	76.3
		PII(D28)	32	22	68.8	50.0	83.9
		PII(D35)	32	23	71.9	53.3	86.3
		PII(D42)	32	23	71.9	53.3	86.3
	H5N1/D4	PRE	28	0	0.0	0.0	12.3
		PI(D7)	28	17	60.7	40.6	78.5
		PI(D14)	28	21	75.0	55.1	89.3
		PI(D21)	28	23	82.1	63.1	93.9
		PII(D28)	28	26	92.9	76.5	99.1
		PII(D35)	28	27	96.4	81.7	99.9
		PII(D42)	28	27	96.4	81.7	99.9
	Control	PRE	49	0	0.0	0.0	7.3
		PI(D7)	49	0	0.0	0.0	7.3
		PI(D14)	49	12	24.5	13.3	38.9
		PI(D21)	49	29	59.2	44.2	73.0
		PII(D28)	49	49	100	92.7	100
		PII(D35)	49	49	100	92.7	100
		PII(D42)	49	48	98.0	89.1	99.9

N = Number of subjects with available results
n/% = Number/percentage of seroprotected subjects (HI titer ≥ 1:40)
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PRE = Pre-vaccination at Day 0
PI(D7) = Post-vaccination one at Day 7
PI(D14) = Post-vaccination one at Day 14
PI(D21) = Post-vaccination one at Day 21
PII(D28) = Post-vaccination two at Day 28
PII(D35) = Post-vaccination two at Day 35
PII(D42) = Post-vaccination two at Day 42

Secondary Outcome Variable(s): SPR for H5N1 HI antibodies against A/Indonesia/05/2005 strain at Day 0 and Month 6 (ATP cohort for persistence)

Antibodies against	**Group**	**Timing**	**N**	**SPR**			
				n	**%**	**95% CI**	
						LL	**UL**
A/Indonesia/05/2005	H5N1/D1	PRE	35	0	0.0	0.0	10.0
		PII(M6)	35	12	34.3	19.1	52.2
	H5N1/D2	PRE	40	1	2.5	0.1	13.2
		PII(M6)	40	12	30.0	16.6	46.5
	H5N1/D3	PRE	36	0	0.0	0.0	9.7
		PII(M6)	36	15	41.7	25.5	59.2
	H5N1/D4	PRE	35	0	0.0	0.0	10.0
		PII(M6)	35	14	40.0	23.9	57.9
	Control	PRE	46	0	0.0	0.0	7.7
		PII(M6)	46	15	32.6	19.5	48.0
	H5N1/D1/Adj	PRE	38	0	0.0	0.0	9.3
		PI(M6)	39	27	69.2	52.4	83.0
	H5N1/D2/Adj	PRE	32	1	3.1	0.1	16.2

		PI(M6)	33	25	75.8	57.7	88.9
	H5N1/D3/Adj	PRE	40	0	0.0	0.0	8.8
		PI(M6)	40	20	50.0	33.8	66.2
	H5N1/D4/Adj	PRE	32	0	0.0	0.0	10.9
		PI(M6)	33	24	72.7	54.5	86.7

N = Number of subjects with available results
n/% = Number/percentage of seroprotected subjects (HI titer ≥ 1:40)
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PRE = Pre-vaccination at Day 0
PI(M6)= Post-vaccination one at Month 6
PII(M6)= Post-vaccination two at Month 6

Secondary Outcome Variable(s): SPR for H5N1 HI antibodies titers against A/Indonesia/05/2005 at Day 0 and Month 12 (ATP cohort for persistence)

Antibodies against	**Group**	**Timing**	**N**	**SPR**			
				n	**%**	**95% CI**	
						LL	**UL**
A/Indonesia/05/2005	H5N1/D1	PRE	32	0	0.0	0.0	10.9
		PII(M12)	32	12	37.5	21.1	56.3
	H5N1/D2	PRE	39	1	2.6	0.1	13.5
		PII(M12)	39	13	33.3	19.1	50.2
	H5N1/D3	PRE	36	0	0.0	0.0	9.7
		PII(M12)	36	17	47.2	30.4	64.5
	H5N1/D4	PRE	33	0	0.0	0.0	10.6
		PII(M12)	33	13	39.4	22.9	57.9
	Control	PRE	44	0	0.0	0.0	8.0
		PII(M12)	44	16	36.4	22.4	52.2
	H5N1/D1/Adj	PRE	36	0	0.0	0.0	9.7
		PI(M12)	37	28	75.7	58.8	88.2
	H5N1/D2/Adj	PRE	29	1	3.4	0.1	17.8
		PI(M12)	30	25	83.3	65.3	94.4
	H5N1/D3/Adj	PRE	39	0	0.0	0.0	9.0
		PI(M12)	39	27	69.2	52.4	83.0
	H5N1/D4/Adj	PRE	31	0	0.0	0.0	11.2
		PI(M12)	31	23	74.2	55.4	88.1

N = Number of subjects with available results
n/% = Number/percentage of seroprotected subjects (HI titer ≥ 1:40)
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PRE = Pre-vaccination at Day 0
PI(M12) = Post-vaccination one at month 12
PII(M12) = Post-vaccination two at month 12

Secondary Outcome Variable(s): SPR for HI antibody titer against A/Indonesia/05/2005 strain at Month 18 (ATP cohort for persistence)

Antibodies against	**Group**	**Timing**		**SPR**			
			N	**n**	**%**	**95% CI**	
						LL	**UL**
A/Indonesia/05/2005	H5N1/D1	PII(M18)	31	8	25.8	11.9	44.6
	H5N1/D2	PII(M18)	36	17	47.2	30.4	64.5
	H5N1/D3	PII(M18)	29	15	51.7	32.5	70.6
	H5N1/D4	PII(M18)	30	19	63.3	43.9	80.1
	Control	PII(M18)	37	5	13.5	4.5	28.8
	H5N1/D1/Adj	PI(M18)	34	22	64.7	46.5	80.3
	H5N1/D2/Adj	PI(M18)	29	20	69.0	49.2	84.7
	H5N1/D3/Adj	PI(M18)	34	22	64.7	46.5	80.3

	H5N1/D4/Adj	PI(M18)	29	21	72.4	52.8	87.3

N = Number of subjects with available results
n/% = Number/percentage of seroprotected subjects (HI titer ≥ 1:40)
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PI(M18) = Post-vaccination one at Month 18
PII(M18) = Post-vaccination two at Month 18

Secondary Outcome Variable(s): SPR for HI antibodies against A/Indonesia/05/2005 at Month 18 and Month 24 (ATP cohort for persistence)

Antibodies against	Group	Timing	N	SPR			
				n	%	95% CI	
						LL	UL
A/Indonesia/05/2005	H5N1/D1	PII(M24)	30	7	23.3	9.9	42.3
	H5N1/D2	PII(M24)	36	5	13.9	4.7	29.5
	H5N1/D3	PII(M24)	29	7	24.1	10.3	43.5
	H5N1/D4	PII(M24)	27	3	11.1	2.4	29.2
	Control	PII(M24)	32	5	15.6	5.3	32.8
	H5N1/D1/Adj	PI(M24)	34	19	55.9	37.9	72.8
	H5N1/D2/Adj	PI(M24)	28	16	57.1	37.2	75.5
	H5N1/D3/Adj	PI(M24)	35	16	45.7	28.8	63.4
	H5N1/D4/Adj	PI(M24)	26	11	42.3	23.4	63.1

N = Number of subjects with available results
n/% = Number/percentage of seroprotected subjects (HI titer ≥ 1:40)
95% CI = 95% confidence interval, LL = Lower Limit, UL = Upper Limit
PII(M18) = Post-vaccination two at Month 18
PII(M24)= Post-vaccination two at Month 24

Secondary Outcome Variable(s): Descriptive Statistics on the frequency of H5N1-specific T-cells (per 10^6 T-cells) for CD4.ALL DOUBLES, CD4 CD40L, CD4 IL-2, CD4 IFN-gamma, CD4 TNF-alpha in the H5N1/D1, H5N1/D1/Adj and Control groups (ATP cohort for immunogenicity)

Test description	Stimulating Ag	Group	Timing	N	GM	SD	Median
CD4 All doubles	H5N1 A/Indonesia	H5N1/D1	PRE	32	660.79	496.52	743.00
			PI(D21)	32	1802.97	1208.54	1945.50
		H5N1/D1/Adj	PRE	38	1078.64	654.49	1370.00
			PI(D21)	38	2556.66	3390.98	2504.00
		Control	PRE	48	432.89	377.17	473.50
			PI(D21)	46	2754.54	1581.91	2721.00
	H5N1 A/Vietnam	H5N1/D1	PRE	32	644.16	574.82	682.50
			PI(D21)	32	1765.43	1194.64	1870.00
		H5N1/D1/Adj	PRE	38	1175.60	680.15	1284.50
			PI(D21)	38	2416.47	3305.79	2640.50
		Control	PRE	48	432.02	415.83	540.00
			PI(D21)	46	2646.63	1477.24	2607.00
CD4 CD40L	H5N1 A/Indonesia	H5N1/D1	PRE	32	644.39	492.62	709.00
			PI(D21)	32	1761.19	1196.26	1874.00
		H5N1/D1/Adj	PRE	38	1058.16	643.00	1363.50
			PI(D21)	38	2499.88	3357.25	2480.00
		Control	PRE	48	440.90	355.90	457.50
			PI(D21)	46	2648.55	1541.56	2633.00
	H5N1 A/Vietnam	H5N1/D1	PRE	32	573.52	563.51	650.00
			PI(D21)	32	1727.26	1185.00	1842.50
		H5N1/D1/Adj	PRE	38	1156.19	662.51	1288.50
			PI(D21)	38	2390.77	3274.91	2652.00
		Control	PRE	48	463.60	397.95	525.50
			PI(D21)	46	2533.08	1441.71	2580.50
CD4 IL-2	H5N1	H5N1/D1	PRE	32	587.33	400.99	641.00

	A/Indonesia		PI(D21)	32	1592.59	1094.85	1616.00
		H5N1/D1/Adj	PRE	38	983.70	611.51	1186.50
			PI(D21)	38	2298.03	3194.75	2291.50
		Control	PRE	48	408.55	342.96	433.50
			PI(D21)	46	2501.31	1491.32	2485.00
	H5N1 A/Vietnam	H5N1/D1	PRE	32	507.35	459.58	599.50
			PI(D21)	32	1553.38	1097.52	1607.00
		H5N1/D1/Adj	PRE	38	1076.57	625.30	1195.50
			PI(D21)	38	2188.25	3132.13	2210.00
		Control	PRE	48	413.90	392.56	473.50
			PI(D21)	46	2394.99	1380.13	2368.50
CD4 INF-γ	H5N1 A/Indonesia	H5N1/D1	PRE	32	421.51	397.84	407.00
			PI(D21)	32	791.95	631.74	785.50
		H5N1/D1/Adj	PRE	38	541.01	408.70	607.00
			PI(D21)	38	1073.88	1705.71	1304.50
		Control	PRE	48	333.32	319.32	357.00
			PI(D21)	46	1088.39	765.10	993.50
	H5N1 A/Vietnam	H5N1/D1	PRE	32	455.09	516.93	470.00
			PI(D21)	32	920.93	696.37	960.50
		H5N1/D1/Adj	PRE	38	656.61	454.29	729.50
			PI(D21)	38	1116.70	1644.28	1105.00
		Control	PRE	48	404.70	360.06	406.50
			PI(D21)	46	1193.80	743.35	1057.50
CD4 TNF-α	H5N1 A/Indonesia	H5N1/D1	PRE	32	459.50	387.67	544.00
			PI(D21)	32	1157.74	804.86	1187.00
		H5N1/D1/Adj	PRE	38	798.84	541.32	944.50
			PI(D21)	38	1817.39	2954.94	1905.50
		Control	PRE	48	253.79	304.29	294.00
			PI(D21)	46	1598.22	865.49	1658.50
	H5N1 A/Vietnam	H5N1/D1	PRE	32	490.29	451.10	490.50
			PI(D21)	32	1194.00	851.13	1360.00
		H5N1/D1/Adj	PRE	38	871.74	554.59	952.50
			PI(D21)	38	1773.33	2882.54	1888.00
		Control	PRE	48	294.27	363.51	357.00
			PI(D21)	46	1640.59	869.81	1616.50

All doubles: T-cells producing at least 2 cytokines
CD4-CD40L: CD4 T-cells producing at least CD40L and another cytokine
CD4-IL-2: CD4 T-cells producing at least IL2 and another cytokine
CD4-INFγ: CD4 T-cells producing at least INF gamma and another cytokine
CD4-TNFα: CD4 T-cells producing at least TNF alpha and another cytokine
N = number of subjects with available results
GM= Geometric Mean
SD = Standard Deviation
PRE = Pre-vaccination at Day 0
PI(D21)= Post-vaccination one at Day 21

Secondary Outcome Variable(s): Descriptive Statistics on the frequency of H5N1-specific T-cells (per 10^6 T-cells) for CD8.ALL DOUBLES, CD8 CD40L, CD8 IL-2, CD8 IFN-gamma, CD8 TNF-alpha in the H5N1/D1, H5N1/D1/Adj and Control groups (ATP cohort for immunogenicity)

Test description	Stimulating Ag	Group	Timing	N	GM	SD	Median
CD8 All doubles	H5N1 A/Indonesia	H5N1/D1	PRE	32	43.01	283.32	71.00
			PI(D21)	32	59.13	254.41	132.50
		H5N1/D1/Adj	PRE	38	37.21	407.20	60.50
			PI(D21)	38	34.93	357.46	75.00

		Control	PRE	48	23.78	236.38	47.50
			PI(D21)	46	37.46	222.35	52.00
	H5N1 A/Vietnam	H5N1/D1	PRE	32	113.63	419.01	159.00
			PI(D21)	32	171.45	511.66	166.50
		H5N1/D1/Adj	PRE	38	57.62	562.31	99.50
			PI(D21)	38	81.20	456.12	153.00
		Control	PRE	48	43.21	302.70	90.50
			PI(D21)	46	91.41	348.74	147.50
CD8 CD40L	H5N1 A/Indonesia	H5N1/D1	PRE	32	1.89	28.23	1.00
			PI(D21)	32	2.57	21.64	1.00
		H5N1/D1/Adj	PRE	38	2.33	73.05	1.00
			PI(D21)	38	2.66	53.14	1.00
		Control	PRE	48	1.76	14.03	1.00
			PI(D21)	46	2.18	21.72	1.00
	H5N1 A/Vietnam	H5N1/D1	PRE	32	2.01	26.33	1.00
			PI(D21)	32	4.91	26.77	1.00
		H5N1/D1/Adj	PRE	38	3.82	58.92	1.00
			PI(D21)	38	3.88	32.08	1.00
		Control	PRE	48	1.99	12.91	1.00
			PI(D21)	46	2.39	17.68	1.00
CD8 IL-2	H5N1 A/Indonesia	H5N1/D1	PRE	32	17.57	174.87	42.50
			PI(D21)	32	16.10	114.95	31.00
		H5N1/D1/Adj	PRE	38	20.54	251.18	40.00
			PI(D21)	38	23.42	186.75	39.00
		Control	PRE	48	15.34	143.08	30.50
			PI(D21)	46	23.49	136.02	39.00
	H5N1 A/Vietnam	H5N1/D1	PRE	32	45.91	203.21	59.50
			PI(D21)	32	75.87	230.51	86.00
		H5N1/D1/Adj	PRE	38	36.40	290.80	48.50
			PI(D21)	38	47.20	226.97	90.50
		Control	PRE	48	23.63	179.05	51.00
			PI(D21)	46	48.25	166.76	86.50
CD IFN-γ	H5N1 A/Indonesia	H5N1/D1	PRE	32	39.09	278.32	92.00
			PI(D21)	32	51.02	252.06	132.50
		H5N1/D1/Adj	PRE	38	27.97	372.78	40.50
			PI(D21)	38	23.17	351.72	56.50
		Control	PRE	48	20.08	227.95	37.50
			PI(D21)	46	28.21	213.38	41.00
	H5N1 A/Vietnam	H5N1/D1	PRE	32	71.55	419.62	152.50
			PI(D21)	32	155.47	508.80	150.00
		H5N1/D1/Adj	PRE	38	53.42	547.34	76.00
			PI(D21)	38	59.86	445.24	127.00
		Control	PRE	48	47.48	286.20	97.50
			PI(D21)	46	90.43	337.45	149.00
CD8 TNF-α	H5N1 A/Indonesia	H5N1/D1	PRE	32	32.04	243.66	80.00
			PI(D21)	32	53.94	231.83	124.50
		H5N1/D1/Adj	PRE	38	23.11	380.50	47.00
			PI(D21)	38	33.62	336.58	75.50
		Control	PRE	48	15.95	200.76	28.00
			PI(D21)	46	18.87	177.64	36.50
	H5N1 A/Vietnam	H5N1/D1	PRE	32	60.38	397.66	98.50
			PI(D21)	32	113.96	447.62	115.00
		H5N1/D1/Adj	PRE	38	49.02	527.31	83.00

			PI(D21)	38	57.38	421.10	98.00
		Control	PRE	48	34.07	243.36	71.00
			PI(D21)	46	51.24	305.14	136.00

All doubles: T-cells producing at least 2 cytokines
CD4-CD40L: CD4 T-cells producing at least CD40L and another cytokine
CD4-IL-2: CD4 T-cells producing at least IL2 and another cytokine
CD4-INFγ: CD4 T-cells producing at least INF gamma and another cytokine
CD4-TNFα: CD4 T-cells producing at least TNF alpha and another cytokine
N = number of subjects with available results
GM= Geometric Mean
SD = Standard Deviation
PRE = Pre-vaccination at Day 0
PI(D21)= Post-vaccination one at Day 21

Secondary Outcome Variable(s): Descriptive Statistics on the frequency of H5N1 –specific T-cells (per million T-cells) for CD4.ALL DOUBLES, CD4.CD40L, CD4.IL-2, CD4.INFγ, CD4.TNFα in the H5N1/D1, H5N1/D1/Adj and Control groups (ATP cohort for persistence)

Test description	Stimulating antigen	Group	Timing	N	GM	SD	Median
CD4 All doubles	H5N1 A/Indonesia	H5N1/D1/Adj	PI(M6)	37	1564.30	1110.97	1575.00
		H5N1/D1	PII(M6)	35	1268.16	690.99	1244.00
		Control	PII(M6)	45	1722.63	924.35	1817.00
	H5N1 A/Vietnam	H5N1/D1/Adj	PI(M6)	37	1597.13	1108.43	1710.00
		H5N1/D1	PII(M6)	35	1171.95	684.10	1138.00
		Control	PII(M6)	45	1624.18	891.84	1775.00
CD4 CD40L	H5N1 A/Indonesia	H5N1/D1/Adj	PI(M6)	37	1523.86	1089.72	1605.00
		H5N1/D1	PII(M6)	35	1234.01	656.25	1190.00
		Control	PII(M6)	45	1673.64	902.15	1720.00
	H5N1 A/Vietnam	H5N1/D1/Adj	PI(M6)	37	1557.69	1098.95	1724.00
		H5N1/D1	PII(M6)	35	1149.17	664.41	1124.00
		Control	PII(M6)	45	1595.66	870.56	1748.00
CD4 IL-2	H5N1 A/Indonesia	H5N1/D1/Adj	PI(M6)	37	1438.69	1060.65	1454.00
		H5N1/D1	PII(M6)	35	1112.40	626.95	1136.00
		Control	PII(M6)	45	1581.47	870.19	1736.00
	H5N1 A/Vietnam	H5N1/D1/Adj	PI(M6)	37	1458.65	1053.54	1481.00
		H5N1/D1	PII(M6)	35	1038.29	627.80	1070.00
		Control	PII(M6)	45	1479.90	824.66	1580.00
CD4 IND-γ	H5N1 A/Indonesia	H5N1/D1/Adj	PI(M6)	37	714.47	525.57	794.00
		H5N1/D1	PII(M6)	35	643.20	462.73	636.00
		Control	PII(M6)	45	821.97	560.58	929.00
	H5N1 A/Vietnam	H5N1/D1/Adj	PI(M6)	37	784.23	535.61	876.00
		H5N1/D1	PII(M6)	35	645.14	533.27	679.00
		Control	PII(M6)	45	857.33	579.43	885.00
CD4 TNF-α	H5N1 A/Indonesia	H5N1/D1/Adj	PI(M6)	37	1175.31	913.53	1152.00
		H5N1/D1	PII(M6)	35	925.40	507.29	920.00
		Control	PII(M6)	45	1335.47	814.96	1467.00
	H5N1 A/Vietnam	H5N1/D1/Adj	PI(M6)	37	1211.05	913.47	1279.00
		H5N1/D1	PII(M6)	35	870.07	510.09	941.00
		Control	PII(M6)	45	1258.08	752.35	1292.00

All doubles: T-cells producing at least 2 cytokines
CD4-CD40L: CD4 T-cells producing at least CD40L and another cytokine
CD4-IL-2: CD4 T-cells producing at least IL2 and another cytokine
CD4-INFγ: CD4 T-cells producing at least INF gamma and another cytokine
CD4-TNFα: CD4 T-cells producing at least TNF alpha and another cytokine
N = number of subjects with available results

GM= Geometric Mean
SD = Standard Deviation
PI(M6) = Post-vaccination one at month 6
PII(M6) = Post-vaccination two at month 6

Secondary Outcome Variable(s): Descriptive Statistics on the frequency of H5N1-specific T-cells (per million T-cells) for CD8.ALL DOUBLES, CD8.CD40L, CD8.IL-2, CD8.TNFα, CD8.INFγ in the H5N1/D1, H5N1/D1/Adj and Control groups (ATP cohort for persistence)

Test description	Stimulating antigen	Group	Timing	N	GM	SD	Median
CD8 All doubles	H5N1 A/Indonesia	H5N1/D1/Adj	PI(M6)	37	33.49	409.93	59.00
		H5N1/D1	PII(M6)	35	47.94	364.53	79.00
		Control	PII(M6)	45	34.04	386.19	89.00
	H5N1 A/Vietnam	H5N1/D1/Adj	PI(M6)	37	56.65	481.42	85.00
		H5N1/D1	PII(M6)	35	81.38	506.71	139.00
		Control	PII(M6)	45	37.30	462.95	107.00
CD8 CD40L	H5N1 A/Indonesia	H5N1/D1/Adj	PI(M6)	37	1.94	12.28	1.00
		H5N1/D1	PII(M6)	35	3.70	15.14	1.00
		Control	PII(M6)	45	2.42	18.26	1.00
	H5N1 A/Vietnam	H5N1/D1/Adj	PI(M6)	37	2.56	25.60	1.00
		H5N1/D1	PII(M6)	35	1.80	13.24	1.00
		Control	PII(M6)	45	1.99	18.18	1.00
CD8 IL-2	H5N1 A/Indonesia	H5N1/D1/Adj	PI(M6)	37	28.01	277.26	52.00
		H5N1/D1	PII(M6)	35	30.84	251.14	54.00
		Control	PII(M6)	45	22.14	244.09	53.00
	H5N1 A/Vietnam	H5N1/D1/Adj	PI(M6)	37	43.30	295.08	93.00
		H5N1/D1	PII(M6)	35	44.72	377.41	77.00
		Control	PII(M6)	45	32.71	273.44	63.00
CD8 IND-γ	H5N1 A/Indonesia	H5N1/D1/Adj	PI(M6)	37	16.08	369.31	29.00
		H5N1/D1	PII(M6)	35	30.58	361.38	49.00
		Control	PII(M6)	45	26.06	347.24	44.00
	H5N1 A/Vietnam	H5N1/D1/Adj	PI(M6)	37	33.15	477.13	48.00
		H5N1/D1	PII(M6)	35	51.80	500.79	117.00
		Control	PII(M6)	45	38.92	454.21	61.00
CD8 TNF-α	H5N1 A/Indonesia	H5N1/D1/Adj	PI(M6)	37	28.97	395.24	52.00
		H5N1/D1	PII(M6)	35	34.87	283.20	71.00
		Control	PII(M6)	45	33.43	334.56	76.00
	H5N1 A/Vietnam	H5N1/D1/Adj	PI(M6)	37	46.52	457.05	73.00
		H5N1/D1	PII(M6)	35	68.28	435.20	123.00
		Control	PII(M6)	45	33.42	416.77	80.00

All doubles: T-cells producing at least 2 cytokines
CD4-CD40L: CD4 T-cells producing at least CD40L and another cytokine
CD4-IL-2: CD4 T-cells producing at least IL2 and another cytokine
CD4-INFγ: CD4 T-cells producing at least INF gamma and another cytokine
CD4-TNFα: CD4 T-cells producing at least TNF alpha and another cytokine
N = number of subjects with available results
GM= Geometric Mean
SD = Standard Deviation
PI(M6) = Post-vaccination one at month 6
PII(M6) = Post-vaccination two at month 6

Secondary Outcome Variable(s): Descriptive Statistics on the frequency cytokine-positive T-cells (per million T-cells) for CD4 CD40L, CD4 ALL DOUBLES, CD4 IL-2, CD4 TNF-α, CD4 INF-γ (ATP cohort for persistence)

Test description	Stimulating antigen	Group	Timing	N	GM	SD	Median
CD4 all doubles	H5N1	H5N1/D1/Adj	PI(M12)	37	1260.43	960.63	1333.00

	A/Indonesia	H5N1/D1	PII(M12)	28	774.86	419.77	786.50
		Control	PII(M12)	44	1181.81	930.36	1332.50
	H5N1 A/Vietnam	H5N1/D1/Adj	PI(M12)	37	1261.55	1037.04	1171.00
		H5N1/D1	PII(M12)	28	761.45	422.84	796.50
		Control	PII(M12)	44	1158.63	1018.79	1225.00
CD4 CD40L	H5N1 A/Indonesia	H5N1/D1/Adj	PI(M12)	37	985.99	961.01	1119.00
		H5N1/D1	PII(M12)	28	607.16	376.45	647.00
		Control	PII(M12)	44	1036.76	769.91	1159.00
	H5N1 A/Vietnam	H5N1/D1/Adj	PI(M12)	37	1031.21	1029.45	1090.00
		H5N1/D1	PII(M12)	28	621.43	387.45	641.00
		Control	PII(M12)	44	1003.50	896.75	1134.00
CD4 IL-2	H5N1 A/Indonesia	H5N1/D1/Adj	PI(M12)	37	1197.38	933.79	1290.00
		H5N1/D1	PII(M12)	28	710.36	418.12	721.00
		Control	PII(M12)	44	1121.63	899.31	1219.50
	H5N1 A/Vietnam	H5N1/D1/Adj	PI(M12)	37	1187.49	995.13	1183.00
		H5N1/D1	PII(M12)	28	703.81	419.13	733.00
		Control	PII(M12)	44	1103.45	973.56	1100.00
CD4 INF-γ	H5N1 A/Indonesia	H5N1/D1/Adj	PI(M12)	37	666.36	471.12	746.00
		H5N1/D1	PII(M12)	28	415.94	250.77	432.50
		Control	PII(M12)	44	570.92	466.67	618.00
	H5N1 A/Vietnam	H5N1/D1/Adj	PI(M12)	37	684.94	537.84	670.00
		H5N1/D1	PII(M12)	28	464.90	264.20	497.50
		Control	PII(M12)	44	600.10	527.83	643.00
CD4 TNF-α	H5N1 A/Indonesia	H5N1/D1/Adj	PI(M12)	37	994.56	851.69	1065.00
		H5N1/D1	PII(M12)	28	574.82	298.98	551.50
		Control	PII(M12)	44	885.67	814.96	997.50
	H5N1 A/Vietnam	H5N1/D1/Adj	PI(M12)	37	1016.89	950.97	945.00
		H5N1/D1	PII(M12)	28	569.54	307.10	616.50
		Control	PII(M12)	44	881.85	891.97	939.50

All doubles: T-cells producing at least 2 cytokines
CD4-CD40L: CD4 T-cells producing at least CD40L and another cytokine
CD4-IL-2: CD4 T-cells producing at least IL2 and another cytokine
CD4-INFγ: CD4 T-cells producing at least INF gamma and another cytokine
CD4-TNFα: CD4 T-cells producing at least TNF alpha and another cytokine
N = number of subjects with available results
GM= Geometric Mean
SD = Standard Deviation
PI(M12) = Post-vaccination one at month 12
PII(M12) = Post-vaccination two at month 12

Secondary Outcome Variable(s): Descriptive Statistics on the frequency cytokine-positive T-cells (per million T-cells) for CD8 ALL DOUBLES, CD8 CD40L, CD8 IL-2, CD8 TNF-α, CD8 INF-γ (ATP cohort for persistence)

Test description	Stimulating antigen	Group	Timing	N	GM	SD	Median
CD8 all doubles	H5N1 A/Indonesia	H5N1/D1/Adj	PI(M12)	37	45.93	331.57	78.00
		H5N1/D1	PII(M12)	28	36.24	242.92	73.00
		Control	PII(M12)	44	11.92	150.60	30.50
	H5N1 A/Vietnam	H5N1/D1/Adj	PI(M12)	37	42.18	488.82	69.00
		H5N1/D1	PII(M12)	28	52.86	350.71	95.00
		Control	PII(M12)	44	13.94	296.53	31.50
CD8 CD40L	H5N1 A/Indonesia	H5N1/D1/Adj	PI(M12)	37	1.87	10.82	1.00
		H5N1/D1	PII(M12)	28	1.40	7.26	1.00
		Control	PII(M12)	44	1.41	14.52	1.00
	H5N1 A/Vietnam	H5N1/D1/Adj	PI(M12)	37	1.39	6.66	1.00
		H5N1/D1	PII(M12)	28	1.53	18.51	1.00

		Control	PII(M12)	44	1.16	4.85	1.00
CD8 IL-2	H5N1 A/Indonesia	H5N1/D1/Adj	PI(M12)	37	30.10	273.92	56.00
		H5N1/D1	PII(M12)	28	20.33	156.45	54.50
		Control	PII(M12)	44	8.91	94.06	5.50
	H5N1 A/Vietnam	H5N1/D1/Adj	PI(M12)	37	28.79	352.07	55.00
		H5N1/D1	PII(M12)	28	31.14	258.90	49.50
		Control	PII(M12)	44	9.40	126.19	13.00
CD8 INF-γ	H5N1 A/Indonesia	HN3_8AD	PI(M12)	37	27.24	286.04	46.00
		H5N1/D1	PII(M12)	28	25.69	239.48	60.50
		Control	PII(M12)	44	8.56	141.61	1.00
	H5N1 A/Vietnam	H5N1/D1/Adj	PI(M12)	37	53.32	453.55	77.00
		H5N1/D1	PII(M12)	28	41.47	326.09	54.00
		Control	PII(M12)	44	14.39	288.56	32.00
CD8TNF-α	H5N1 A/Indonesia	H5N1/D1/Adj	PI(M12)	37	31.33	289.82	54.00
		H5N1/D1	PII(M12)	28	26.52	212.16	62.00
		Control	PII(M12)	44	10.22	114.43	23.50
	H5N1 A/Vietnam	H5N1/D1/Adj	PI(M12)	37	34.23	442.43	55.00
		H5N1/D1	PII(M12)	28	41.76	298.96	75.50
		Control	PII(M12)	44	14.22	261.75	31.50

All doubles: T-cells producing at least 2 cytokines
CD4-CD40L: CD4 T-cells producing at least CD40L and another cytokine
CD4-IL-2: CD4 T-cells producing at least IL2 and another cytokine
CD4-INFγ: CD4 T-cells producing at least INF gamma and another cytokine
CD4-TNFα: CD4 T-cells producing at least TNF alpha and another cytokine
N = number of subjects with available results
GM= Geometric Mean
SD = Standard Deviation
PI(M12) = Post-vaccination one at month 12
PII(M12) = Post-vaccination two at month 12

Secondary Outcome Variable(s): Descriptive Statistics on the frequency cytokine-positive T-cells (per million T-cells) for CD4.CD40L, CD4.ALL DOUBLE, CD4.IL-2, CD4.TNFα, CD4.INFγ, at Month 18 (ATP cohort for persistence)

Test description	Stimulating antigen	Group	Timing	N	GM	SD	Median
CD4.ALL DOUBLE	H5N1 A/Indonesia	H5N1/D1/Adj	PI(M18)	33	1242.56	1104.08	1421.00
		H5N1/D1	PII(M18)	31	1052.71	824.87	1052.00
		Control	PII(M18)	37	1369.84	1071.51	1392.00
	H5N1 A/Vietnam	H5N1/D1/Adj	PI(M18)	33	1291.06	1065.90	1536.00
		H5N1/D1	PII(M18)	31	1022.20	897.94	1022.00
		Control	PII(M18)	37	1342.20	1121.68	1367.00
CD4.CD40L	H5N1 A/Indonesia	H5N1/D1/Adj	PI(M18)	33	1205.78	1096.35	1369.00
		H5N1/D1	PII(M18)	31	892.79	817.81	1013.00
		Control	PII(M18)	37	1339.31	1050.75	1330.00
	H5N1 A/Vietnam	H5N1/D1/Adj	PI(M18)	33	1245.03	1065.21	1523.00
		H5N1/D1	PII(M18)	31	1001.37	874.61	1036.00
		Control	PII(M18)	37	1322.22	1111.19	1288.00
CD4.IL-2	H5N1 A/Indonesia	H5N1/D1/Adj	PI(M18)	33	1110.86	1056.55	1316.00
		H5N1/D1	PII(M18)	31	929.36	667.73	946.00
		Control	PII(M18)	37	1166.17	930.43	1170.00
	H5N1 A/Vietnam	H5N1/D1/Adj	PI(M18)	33	1133.41	1025.45	1346.00
		H5N1/D1	PII(M18)	31	885.27	700.13	933.00
		Control	PII(M18)	37	1162.28	922.38	1062.00
CD4.INFγ	H5N1 A/Indonesia	H5N1/D1/Adj	PI(M18)	33	819.54	691.21	906.00
		H5N1/D1	PII(M18)	31	756.14	744.88	729.00

		Control	PII(M18)	37	827.07	803.02	865.00
	H5N1 A/Vietnam	H5N1/D1/Adj	PI(M18)	33	868.55	652.52	1042.00
		H5N1/D1	PII(M18)	31	763.47	794.96	743.00
		Control	PII(M18)	37	871.03	836.12	965.00
CD4.TNFα	H5N1 A/Indonesia	H5N1/D1/Adj	PI(M18)	33	963.39	948.91	1173.00
		H5N1/D1	PII(M18)	311	855.32	563.81	811.00
		Control	PII(M18)	37	1051.05	827.99	1035.00
	H5N1 A/Vietnam	H5N1/D1/Adj	PI(M18)	33	1001.02	928.11	1074.00
		H5N1/D1	PII(M18)	31	791.80	619.88	793.00
		Control	PII(M18)	37	1031.21	847.64	1079.00

All doubles: T-cells producing at least 2 cytokines
N = number of subjects with available results
GM= Geometric Mean
SD = Standard Deviation
PI(M18) = Post-vaccination one at month 18
PII(M18) = Post-vaccination two at month 18

Secondary Outcome Variable(s): Descriptive Statistics on the frequency cytokine-positive T-cells (per million T-cells) for CD4 CD40L, CD4 ALL DOUBLES, CD4 IL-2, CD4 TNF-α, CD4 INF-γ at Month 18 and Month 24 (ATP cohort for persistence)

Test description	Stimulating antigen	Group	Timing	N	GM	SD	Median
CD4 all doubles	H5N1 A/Indonesia	H5N1/D1/Adj	PI(M24)	33	1012.56	944.60	1307.00
		H5N1/D1	PII(M24)	31	926.15	447.45	914.00
		Control	PII(M24)	37	1079.70	674.14	1306.00
	H5N1 A/Vietnam	H5N1/D1/Adj	PI(M24)	33	999.47	975.01	1229.00
		H5N1/D1	PII(M24)	31	879.22	467.43	850.00
		Control	PII(M24)	37	1096.97	719.71	1322.00
CD4 CD40L	H5N1 A/Indonesia	H5N1/D1/Adj	PI(M24)	33	988.34	915.67	1220.00
		H5N1/D1	PII(M24)	31	906.31	451.56	917.00
		Control	PII(M24)	37	1059.22	660.08	1280.00
	H5N1 A/Vietnam	H5N1/D1/Adj	PI(M24)	33	985.13	958.74	1195.00
		H5N1/D1	PII(M24)	31	864.14	471.46	826.00
		Control	PII(M24)	37	1071.48	713.51	1356.00
CD4 IL-2	H5N1 A/Indonesia	H5N1/D1/Adj	PI(M24)	33	904.12	888.45	1146.00
		H5N1/D1	PII(M24)	31	811.98	437.11	867.00
		Control	PII(M24)	37	913.13	600.97	1105.00
	H5N1 A/Vietnam	H5N1/D1/Adj	PI(M24)	33	922.08	929.56	1101.00
		H5N1/D1	PII(M24)	31	756.57	452.93	839.00
		Control	PII(M24)	37	918.62	622.41	1253.00
CD4 INF-γ	H5N1 A/Indonesia	H5N1/D1/Adj	PI(M24)	33	755.86	627.96	848.00
		H5N1/D1	PII(M24)	31	649.73	320.59	654.00
		Control	PII(M24)	37	584.41	473.81	860.00
	H5N1 A/Vietnam	H5N1/D1/Adj	PI(M24)	33	725.85	684.03	838.00
		H5N1/D1	PII(M24)	31	633.64	358.32	704.00
		Control	PII(M24)	37	712.49	527.78	888.00
CD4 TNF-α	H5N1 A/Indonesia	H5N1/D1/Adj	PI(M24)	33	808.80	843.77	1062.00
		H5N1/D1	PII(M24)	31	735.48	369.25	773.00
		Control	PII(M24)	37	867.78	561.40	1186.00
	H5N1 A/Vietnam	H5N1/D1/Adj	PI(M24)	33	869.78	828.12	999.00
		H5N1/D1	PII(M24)	31	668.49	371.92	680.00
		Control	PII(M24)	37	861.01	601.29	1023.00

All doubles: T-cells producing at least 2 cytokines
CD4-CD40L: CD4 T-cells producing at least CD40L and another cytokine
CD4-IL-2: CD4 T-cells producing at least IL2 and another cytokine
CD4-INFγ: CD4 T-cells producing at least INF gamma and another cytokine

CD4-TNFα: CD4 T-cells producing at least TNF alpha and another cytokine
N = number of subjects with available results
GM= Geometric Mean
SD = Standard Deviation
PI(M18)= Post-vaccination one at month 18
PI(M24) = Post-vaccination one at month 24
PII(M18) = Post-vaccination two at month 18
PII(M24) = Post-vaccination two at month 24

Secondary Outcome Variable(s): Descriptive Statistics on the frequency cytokine-positive T-cells (per million T-cells) for CD8.ALL DOUBLE, CD8.CD40L, CD8.IL-2, CD8.TNFα, CD8.INFγ (ATP cohort for persistence)

Test description	Stimulating antigen	Group	Timing	N	GM	Mean	SD	Median
CD8.ALL DOUBLE	H5N1 A/Indonesia	H5N1/D1/Adj	PI(M18)	33	18.40	145.52	355.65	35.00
		H5N1/D1	PII(M18)	31	22.51	146.55	255.96	82.00
		Control	PII(M18)	37	18.68	144.00	276.92	40.00
	H5N1 A/Vietnam	H5N1/D1/Adj	PI(M18)	33	21.98	175.97	456.26	48.00
		H5N1/D1	PII(M18)	31	48.38	214.45	365.41	66.00
		Control	PII(M18)	37	59.01	226.14	338.51	119.00
CD8.CD40L	H5N1 A/Indonesia	H5N1/D1/Adj	PI(M18)	33	4.05	19.15	29.87	1.00
		H5N1/D1	PII(M18)	31	2.40	12.26	22.58	1.00
		Control	PII(M18)	37	4.35	31.43	62.39	1.00
	H5N1 A/Vietnam	H5N1/D1/Adj	PI(M18)	33	6.47	33.45	44.91	1.00
		H5N1/D1	PII(M18)	31	2.55	18.26	39.96	1.00
		Control	PII(M18)	37	5.97	36.49	48.45	1.00
CD8.IL-2	H5N1 A/Indonesia	H5N1/D1/Adj	PI(M18)	33	7.26	90.18	266.43	1.00
		H5N1/D1	PII(M18)	31	15.90	79.61	123.44	43.00
		Control	PII(M18)	37	12.01	76.70	122.88	30.00
	H5N1 A/Vietnam	H5N1/D1/Adj	PI(M18)	33	7.94	106.12	324.29	1.00
		H5N1/D1	PII(M18)	31	18.60	105.97	169.97	40.00
		Control	PII(M18)	37	25.37	105.57	149.04	47.00
CD8.INFγ	H5N1 A/Indonesia	H5N1/D1/Adj	PI(M18)	33	18.34	136.85	336.85	38.00
		H5N1/D1	PII(M18)	31	24.85	148.52	259.32	82.00
		Control	PII(M18)	37	16.65	140.49	269.56	31.00
	H5N1 A/Vietnam	H5N1/D1/Adj	PI(M18)	33	22.03	176.06	447.63	48.00
		H5N1/D1	PII(M18)	31	43.90	213.58	362.99	62.00
		Control	PII(M18)	37	53.25	223.95	336.54	119.00
CD8.TNFα	H5N1 A/Indonesia	H5N1/D1/Adj	PI(M18)	33	10.89	121.88	295.13	1.00
		H5N1/D1	PII(M18)	31	32.03	149.84	211.28	81.00
		Control	PII(M18)	37	19.01	103.54	235.02	42.00
	H5N1 A/Vietnam	H5N1/D1/Adj	PI(M18)	33	16.84	150.73	418.97	38.00
		H5N1/D1	PII(M18)	31	52.90	193.55	310.96	65.00
		Control	PII(M18)	37	46.57	181.11	299.72	107.00

All doubles: T-cells producing at least 2 cytokines
N = number of subjects with available results
Nmiss = number of subjects with missing results
GM= Geometric Mean
SD = Standard Deviation
PI(M18) = Post-vaccination one at month 18
PII(M18) = Post-vaccination two at month 18

Secondary Outcome Variable(s): Descriptive Statistics on the frequency cytokine-positive T-cells (per million T-cells) for CD8 ALL DOUBLES, CD8 CD40L, CD8 IL-2, CD8 TNF-α, CD8 INF-γ at Month 18 and Month 24 (ATP cohort for persistence)

Test description	Stimulating antigen	Group	Timing	N	GM	Mean	SD	Median
CD4 all doubles	H5N1 A/Indonesia	H5N1/D1/Adj	PI(M24)	33	24.12	155.58	269.62	78.00

		H5N1/D1	PII(M24)	31	25.40	163.13	231.20	73.00
		Control	PII(M24)	37	17.07	90.35	102.42	65.00
	H5N1 A/Vietnam	H5N1/D1/Adj	PI(M24)	33	19.40	187.06	383.27	29.00
		H5N1/D1	PII(M24)	31	29.42	172.97	269.71	73.00
		Control	PII(M24)	37	40.57	177.03	209.17	102.00
CD4 CD40L	H5N1 A/Indonesia	H5N1/D1/Adj	PI(M24)	33	10.04	42.36	48.82	26.00
		H5N1/D1	PII(M24)	31	5.59	27.19	40.72	1.00
		Control	PII(M24)	37	5.03	28.92	46.31	1.00
	H5N1 A/Vietnam	H5N1/D1/Adj	PI(M24)	33	4.93	27.33	41.63	1.00
		H5N1/D1	PII(M24)	31	4.95	29.23	48.14	1.00
		Control	PII(M24)	37	7.91	44.78	62.08	1.00
CD4 IL-2	H5N1 A/Indonesia	H5N1/D1/Adj	PI(M24)	33	10.10	81.73	189.68	21.00
		H5N1/D1	PII(M24)	31	13.14	90.00	153.24	25.00
		Control	PII(M24)	37	10.75	42.54	49.43	32.00
	H5N1 A/Vietnam	H5N1/D1/Adj	PI(M24)	33	9.45	113.82	313.77	1.00
		H5N1/D1	PII(M24)	31	14.62	102.35	200.16	26.00
		Control	PII(M24)	37	17.08	87.32	107.69	31.00
CD4 INF-γ	H5N1 A/Indonesia	H5N1/D1/Adj	PI(M24)	33	25.32	158.03	269.48	64.00
		H5N1/D1	PII(M24)	31	24.13	159.58	227.06	93.00
		Control	PII(M24)	37	19.27	87.32	96.17	65.00
	H5N1 A/Vietnam	H5N1/D1/Adj	PI(M24)	33	21.42	188.27	373.22	31.00
		H5N1/D1	PII(M24)	31	28.18	171.06	263.47	73.00
		Control	PII(M24)	37	46.01	174.30	197.73	102.00
CD4 TNF-α	H5N1 A/Indonesia	H5N1/D1/Adj	PI(M24)	33	14.22	122.48	230.22	26.00
		H5N1/D1	PII(M24)	31	21.09	125.84	194.64	57.00
		Control	PII(M24)	37	17.52	66.95	73.04	55.00
	H5N1 A/Vietnam	H5N1/D1/Adj	PI(M24)	33	15.59	155.36	343.03	37.00
		H5N1/D1	PII(M24)	31	20.01	134.06	229.08	45.00
		Control	PII(M24)	37	31.73	132.73	172.02	64.00

All doubles: T-cells producing at least 2 cytokines
CD4-CD40L: CD4 T-cells producing at least CD40L and another cytokine
CD4-IL-2: CD4 T-cells producing at least IL2 and another cytokine
CD4-INFγ: CD4 T-cells producing at least INF gamma and another cytokine
CD4-TNFα: CD4 T-cells producing at least TNF alpha and another cytokine
N = number of subjects with available results
GM= Geometric Mean
SD = Standard Deviation
PI(M18)= Post-vaccination one at month 18
PI(M24) = Post-vaccination one at month 24
PII(M18) = Post-vaccination two at month 18
PII(M24) = Post-vaccination two at month 24

Safety Results: Number (%) of subjects with unsolicited adverse events during the 21 days after the first vaccination and the 30 days after the second vaccination for non-adjuvanted and control groups (Total Vaccinated Cohort)

Most frequent adverse events - On-Therapy (occurring within Day 0-20 following the first vaccination and 30 days after the second vaccination)	**H5N1/D1 Group N=36**	**H5N1/D2 Group N=40**	**H5N1/D3 Group N=37**	**H5N1/D4 Group N=36**	**Control Group N=50**
Subjects with any AE(s), n (%)	22(61.1)	24(60.0)	21(56.8)	26(72.2)	33(66.0)
Subjects with grade 3 AE(s), n (%)	2(5.6)	4(10.0)	1(2.7)	3(8.3)	6(12.0)
Subjects with related AE(s), n (%)	4(11.1)	1(2.5)	4(10.8)	1(2.8)	8(16.0)
Arthralgia	2(5.6)	-	-	-	-
Back pain	2(5.6)	-	-	-	-
Cough	-	-	2(5.4)	-	-
Diarrhoea	2(5.6)	3(7.5)	-	-	4(8.0)

Dyspepsia	-	3(7.5)	-	-	-
Headache	4(11.1)	5(12.5)	5(13.5)	8(22.2)	8(16.0)
Injection site reaction	2(5.6)	-	-	-	4(8.0)
Insomnia	-	-	-	3(8.3)	-
Musculoskeletal stiffness	2(5.6)	-	-	-	-
Nausea	-	-	2(5.4)	-	-
Pharyngolaryngeal pain	-	5(12.5)	3(8.1)	2(5.6)	7(14.0)
Productive cough	-	-	-	-	4(8.0)
Rhinitis	3(8.3)	3(7.5)	3(8.1)	2(5.6)	5(10.0)
Upper respiratory tract infection	3(8.3)	3(7.5)	3(8.1)	8(22.2)	5(10.0)
- : Adverse event absent or not meeting the selected rule: If more than 30 subjects per group and > 3 groups, then only the 5 most frequent adverse events in each group are to be listed. Grade 3 AE= event which prevented normal, everyday activities Related AE= event assessed by the investigator as causally related to the study vaccine					
Safety Results: Number (%) of subjects with unsolicited adverse events during the 30-day follow-up period after the single vaccination for adjuvanted groups (Total Vaccinated Cohort)					
Most frequent adverse events - On-Therapy (occurring within 30 days follow-up period after the single vaccination)	**H5N1/D1/Adj Group N=40**	**H5N1/D2/Adj Group N=35**	**H5N1/D3/Adj Group N=41**	**H5N1/D4/Adj Group N=35**	
Subjects with any AE(s), n (%)	13(32.5)	17(48.6)	17(41.5)	17(48.6)	
Subjects with grade 3 AE(s), n (%)	3(7.5)	2(5.7)	5(12.2)	2(5.7)	
Subjects with related AE(s), n (%)	5(12.5)	4(11.4)	4(9.8)	4(11.4)	
Abdominal discomfort	-	1(2.9)	-	-	
Abdominal pain	-	1(2.9)	-	-	
Back pain	2(5.0)	1(2.9)	2(4.9)	-	
Cough	-	1(2.9)	-	-	
Diarrhoea	2(5.0)	1(2.9)	-	2(5.7)	
Dizziness	-	-	2(4.9)	-	
Dyspepsia	-	1(2.9)	2(4.9)	-	
Fatigue	-	1(2.9)	-	-	
Hangover	-	1(2.9)	-	-	
Headache	-	2(5.7)	2(4.9)	3(8.6)	
Influenza like illness	-	-	2(4.9)	-	
Injection site pruritus	-	-	-	4(11.4)	
Injection site reaction	-	3(8.6)	-	-	
Joint sprain	-	1(2.9)	-	-	
Nausea	2(5.0)	2(5.7)	-	-	
Neck pain	2(5.0)	-	-	-	
Nephrolithiasis	-	1(2.9)	-	-	
Pharyngolaryngeal pain	-	-	-	2(5.7)	
Productive cough	2(5.0)	-	-	-	
Pruritus	-	1(2.9)	-	-	
Rash vesicular	-	1(2.9)	-	-	
Rhinitis	-	1(2.9)	2(4.9)	4(11.4)	
Sensation of heaviness	-	1(2.9)	-	-	
Tendonitis	-	1(2.9)	-	-	
Tooth abscess	-	1(2.9)	-	-	
Upper respiratory tract infection	-	3(8.6)	-	-	
Urinary tract infection	-	1(2.9)	-	-	
- : Adverse event absent or not meeting the selected rule: If more than 30 subjects per group and > 3 groups, then only the 5 most frequent adverse events in each group are to be listed. Grade 3 AE= event which prevented normal, everyday activities Related AE= event assessed by the investigator as causally related to the study vaccine					

Safety results: Number (%) of subjects with SAEs between Day 0 and Day 180 for non-adjuvanted and control groups (Total Vaccinated Cohort)					
Serious adverse event, n (%) [n considered by the investigator to be related to study medication]					
All SAEs	**H5N1/D1 Group N=36**	**H5N1/D2 Group N=40**	**H5N1/D3 Group N=37**	**H5N1/D4 Group N=36**	**Control Group N=50**
Subjects with any SAE(s), n (%) [n assessed by investigator as related]	1(2.8)[0]	1(2.5)[0]	1(2.7)[0]	0(0.0)[0]	3(6.0)[0]
Abdominal pain	0(0.0)[0]	1(2.5)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]
Appendicitis	0(0.0)[0]	0(0.0)[0]	1(2.7)[0]	0(0.0)[0]	0(0.0)[0]
Gastroenteritis	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]
Pneumonia	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]
Tibia fracture	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	1(2.0)[0]
Wrist fracture	1(2.8)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]
Intervertebral disc protrusion	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	1(2.0)[0]
Osteoarthritis	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]
High grade b-cell lymphoma burkitt-like lymphoma	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	1(2.0)[0]
Fatal SAEs	**H5N1/D1 Group N=36**	**H5N1/D2 Group N=40**	**H5N1/D3 Group N=37**	**H5N1/D4 Group N=36**	**Control Group N=50**
Subjects with fatal SAE(s), n (%) [n assessed by investigator as related]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]

Safety results: Number (%) of subjects with SAEs between Day 0 and Day 180 for adjuvanted groups (Total Vaccinated Cohort)				
Serious adverse event, n (%) [n considered by the investigator to be related to study medication]				
All SAEs	**H5N1/D1/Adj Group N=40**	**H5N1/D2/Adj Group N=35**	**H5N1/D3/Adj Group N=41**	**H5N1/D4/Adj Group N=35**
Subjects with any SAE(s), n (%) [n assessed by investigator as related]	1(2.5)[0]	0(0.0)[0]	1(2.4)[0]	0(0.0)[0]
Abdominal pain	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]
Appendicitis	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]
Gastroenteritis	1(2.5)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]
Pneumonia	0(0.0)[0]	0(0.0)[0]	1(2.4)[0]	0(0.0)[0]
Tibia fracture	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]
Wrist fracture	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]
Intervertebral disc protrusion	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]
Osteoarthritis	1(2.5)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]
High grade b-cell lymphoma burkitt-like lymphoma	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]
Fatal SAEs	**H5N1/D1/Adj Group N=40**	**H5N1/D2/Adj Group N=35**	**H5N1/D3/Adj Group N=41**	**H5N1/D4/Adj Group N=35**
Subjects with fatal SAE(s), n (%) [n assessed by investigator as related]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]	0(0.0)[0]

Safety results: Number (%) of subjects with SAEs between Month 6 (Day 180) and Month 12 for non-adjuvanted and control groups (Total Vaccinated Cohort)					
Serious adverse event, n (%) [n considered by the investigator to be related to study medication]					
All SAEs	**H5N1/D1 Group N = 36**	**H5N1/D2 Group N = 40**	**H5N1/D3 Group N = 37**	**H5N1/D4 Group N = 36**	**Control Group N = 50**
Subjects with any SAE(s), n (%) [n assessed by investigator as related]	2 (5.6) [0]	1 (2.5) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]

Foot deformity	1 (2.8) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Jaw fracture	0 (0.0) [0]	1 (2.5) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Multiple injuries	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Nephrolithiasis	1 (2.8) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Tooth fracture	0 (0.0) [0]	1 (2.5) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Traumatic fracture	0 (0.0) [0]	1 (2.5) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Fatal SAEs	**H5N1/D1 Group N = 36**	**H5N1/D2 Group N = 40**	**H5N1/D3 Group N = 37**	**H5N1/D4 Group N = 36**	**Control Group N = 50**
Subjects with fatal SAE(s), n (%) [n assessed by investigator as related]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Safety results: Number (%) of subjects with SAEs between Month 6 (Day 180) and Month 12 for adjuvanted groups (Total Vaccinated Cohort)					
Serious adverse event, n (%) [n considered by the investigator to be related to study medication]					
All SAEs	**H5N1/D1/Adj Group N = 40**	**H5N1/D2/Adj Group N = 35**	**H5N1/D3/Adj Group N = 41**	**H5N1/D4/Adj Group N = 35**	
Subjects with any SAE(s), n (%) [n assessed by investigator as related]	0 (0.0) [0]	0 (0.0) [0]	1 (2.4) [0]	0 (0.0) [0]	
Foot deformity	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	
Jaw fracture	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	
Multiple injuries	0 (0.0) [0]	0 (0.0) [0]	1 (2.4) [0]	0 (0.0) [0]	
Nephrolithiasis	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	
Tooth fracture	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	
Traumatic fracture	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	
Fatal SAEs	**H5N1/D1/Adj Group N = 40**	**H5N1/D2/Adj Group N = 35**	**H5N1/D3/Adj Group N = 41**	**H5N1/D4/Adj Group N = 35**	
Subjects with fatal SAE(s), n (%) [n assessed by investigator as related]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	
Safety results: Number (%) of subjects with SAEs between Month 12 and Month 18 for non-adjuvanted and control groups (Total Vaccinated Cohort)					
Serious adverse event, n (%) [n considered by the investigator to be related to study medication]					
All SAEs	**H5N1/D1 Group N = 36**	**H5N1/D2 Group N = 40**	**H5N1/D3 Group N = 37**	**H5N1/D4 Group N = 36**	**Control Group N = 50**
Subjects with any SAE(s), n (%) [n assessed by investigator as related]	1 (2.8) [0]	1 (2.5) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Abscess	1 (2.8) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Arrhythmia	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Chest pain	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Intestinal obstruction	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Pericarditis	0 (0.0) [0]	1 (2.5) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Pre-eclampsia	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Fatal SAEs	**H5N1/D1 Group N = 36**	**H5N1/D2 Group N = 40**	**H5N1/D3 Group N = 37**	**H5N1/D4 Group N = 36**	**Control Group N = 50**
Subjects with fatal SAE(s), n (%) [n assessed by investigator as related]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Safety results: Number (%) of subjects with SAEs between Month 12 and Month 18 for adjuvanted groups (Total Vaccinated Cohort)					
Serious adverse event, n (%) [n considered by the investigator to be related to study medication]					
All SAEs	**H5N1/D1/Adj Group**	**H5N1/D2/Adj Group**	**H5N1/D3/Adj Group**	**H5N1/D4/Adj Group**	

	N = 40	N = 35	N = 41	N = 35
Subjects with any SAE(s), n (%) [n assessed by investigator as related]	0 (0.0) [0]	0 (0.0) [0]	1 (2.4) [0]	2 (5.7) [0]
Abscess	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Arrhythmia	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (2.9) [0]
Chest pain	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (2.9) [0]
Intestinal obstruction	0 (0.0) [0]	0 (0.0) [0]	1 (2.4) [0]	0 (0.0) [0]
Pericarditis	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Pre-eclampsia	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (2.9) [0]
Fatal SAEs	**H5N1/D1/Adj Group N = 40**	**H5N1/D2/Adj Group N = 35**	**H5N1/D3/Adj Group N = 41**	**H5N1/D4/Adj Group N = 35**
Subjects with fatal SAE(s), n (%) [n assessed by investigator as related]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]

Safety results: Number (%) of subjects with SAEs between Month 18 and Month 24 for non-adjuvanted and control groups (Total Vaccinated Cohort)

Serious adverse event, n (%) [n considered by the investigator to be related to study medication]

All SAEs	**H5N1/D1 Group N = 36**	**H5N1/D2 Group N = 40**	**H5N1/D3 Group N = 37**	**H5N1/D4 Group N = 36**	**Control Group N = 50**
Subjects with any SAE(s), n (%) [n assessed by investigator as related]	1 (2.8) [0]	1 (2.5) [0]	1 (2.7) [0]	0 (0.0) [0]	0 (0.0) [0]
Aortic aneurysm rupture	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Atrial fibrillation	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Foot deformity	0 (0.0) [0]	0 (0.0) [0]	1 (2.7) [0]	0 (0.0) [0]	0 (0.0) [0]
Major depression	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Osteoarthritis	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Pericarditis	0 (0.0) [0]	1 (2.5) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Renal colic	1 (2.8) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Fatal SAEs	**H5N1/D1 Group N = 36**	**H5N1/D2 Group N = 40**	**H5N1/D3 Group N = 37**	**H5N1/D4 Group N = 36**	**Control Group N = 50**
Subjects with fatal SAE(s), n (%) [n assessed by investigator as related]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]

Safety results: Number (%) of subjects with SAEs between Month 18 and Month 24 for adjuvanted groups (Total Vaccinated Cohort)

Serious adverse event, n (%) [n considered by the investigator to be related to study medication]

All SAEs	**H5N1/D1/Adj Group N = 40**	**H5N1/D2/Adj Group N = 35**	**H5N1/D3/Adj Group N = 41**	**H5N1/D4/Adj Group N = 35**
Subjects with any SAE(s), n (%) [n assessed by investigator as related]	1 (2.5) [0]	0 (0.0) [0]	1 (2.4) [0]	2 (5.7) [0]
Aortic aneurysm rupture	0 (0.0) [0]	0 (0.0) [0]	1 (2.4) [0]	0 (0.0) [0]
Atrial fibrillation	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (2.9) [0]
Foot deformity	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Major depression	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (2.9) [0]
Osteoarthritis	1 (2.5) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Pericarditis	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Renal colic	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Fatal SAEs	**H5N1/D1/Adj Group N = 40**	**H5N1/D2/Adj Group N = 35**	**H5N1/D3/Adj Group N = 41**	**H5N1/D4/Adj Group N = 35**
Subjects with fatal SAE(s), n (%) [n assessed by investigator as related]	0 (0.0) [0]	0 (0.0) [0]	1 (2.4) [0]	1 (2.9) [0]
Aortic aneurysm rupture	0 (0.0) [0]	0 (0.0) [0]	1 (2.4) [0]	0 (0.0) [0]

Major depression	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]	1 (2.9) [0]

Conclusion:
Between Month 6 and Month 12, at least one SAE was reported by 2 subjects in the H5N1/D1 Group and 1 subject each in the H5N1/D2 and H5N1/D3/Adj Groups. Between Month 12 and Month 18, at least one SAE was reported by 2 subjects in the H5N1/D4/Adj Group and 1 subject each in the H5N1/D1, H5N1/D2 and H5N1/D3/Adj Groups. Between Month 18 and Month 24, at least one SAE was reported by 2 subjects in the H5N1/D4/Adj Group and 1 subject each in the H5N1/D1, H5N1/D2, H5N1/D3, H5N1/D1/Adj and H5N1/D3/Adj Groups.
None of the SAEs reported up to Month 24 were assessed by the investigators as causally related to the study vaccination.
No fatal SAEs were reported up to Month 18. 2 fatal SAEs (in the H5N1/D3/Adj and the H5N1/D4/Adj groups) were reported between Month 18 and Month 24.

Date updated: 04-September-2014